United States Court of Appeals

for the Second Circuit

APPENDIX

76-1364

In the

United States Court of Appeals

For the Second Circuit

United States of America,

Plaintiff-Appellee,

—against—

Martin Weiner and Edward Pastor,

Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

DEFENDANTS-APPELLANTS' JOINT APPENDIX

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Fischetti & Shargel
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New York, New York 10019
212/586-3732

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Attorneys for Appellant Pastor
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UNITED STATES COURT OF APPEALS
FILED
NOV 15 1976
A. DANIEL FUSARO, CLERK
SECOND CIRCUIT

PAGINATION AS IN ORIGINAL COPY

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January 4, 1977

Hon. A. Daniel Fusaro
Clerk
United States Court of Appeals
for the Second Circuit
Room 1701
United States Courthouse
Foley Square
New York, N. Y. 10007

B
76-1364

Re: United States v. Pastor and Weiner
Dkt. #76-1364

Dear Sir:

We write to make a correction in the Appendix that was filed in mid-November in the above indicated appeal.

Although the index to that Appendix shows "Affidavit of Leslie A. Kuhn, M.D., P.C., dated May 19th, 1976" appearing at Appendix page 311, erroneously we reproduced at that page the same May 18th affidavit of Dr. Kuhn that -- properly indexed -- appears at Appendix page 310.

I have enclosed multiple copies of the May 19, 1976 affidavit that should have been reproduced at Appendix page 311, and respectfully request that it be inserted in the Appendix already on file with the Court at the appropriate page (311).

Our sincere apologies for this error in preparing the Appendix.

Very truly yours,

Richard H. Kuh

RHK:ds
Encs.
cc.&encs.: John J. Kenney, Esq.
Assistant United States Attorney

Gerald L. Shargel, Esq.

Rec'd 1-7-77 ds

LESLIE A. KUHN, M.D., P.C.
THE MOUNT SINAI HOSPITAL
1176 FIFTH AVENUE
NEW YORK, N. Y. 10029

TELEPHONE (212) TRAFALGAR 6-9009

May 19, 1976

Leslie A. Kuhn, M.D., being duly sworn, deposes and says:

This will supplement my previous communication regarding Mr. Edward Pastor. Mr. Pastor has a history of advanced coronary artery disease with extensive narrowing or complete obstruction of all the major arteries supplying the heart. There is a history of hypertension, severe angina pectoris with recurrent episodes of diminished blood flow into the heart muscle. On May 18, 1976, he experienced two hours of severe, crushing anterior chest pain with radiation to the left arm. This was unrelieved by 20 Nitroglycerin tablets.

On examination in the emergency room of Mt. Sinai Hospital (the details of which have been previously submitted), Mr. Pastor had electrocardiographic evidence of diminished blood flow into the heart muscle as well as previous myocardial infarction. Because of the prolonged episode of insufficient blood flow into the heart muscle , because of the prolonged nature of his pain, and because of the new electrocardiographic abnormalities he was hospitalized in the coronary care unit of Mt. Sinai Hospital.

Since his hospitalization Mr. Pastor has had recurrent severe chest pain indicative of inadequate blood flow into the heart muscle. There havebeen some further electrocardiographic abnormalities. These episodes of pain have not responded to Nitroglycerin and he required injections of pain relieving medication.

Mr. Pastor has established severe triple vessel coronary artery disease with episodes of severe diminution of blood supply to the heart muscle manifested at an accelerated pace during the last two days. The emotional tension associated with his trial I believe is an important contributory factor to the development of his episodes of myocardial ischemia. His current clinical status is extremely labile and he may be considered as either undergoing an acute myocardial infarction at this time or having an impending myocardial infarction at this time. I believe that adequate and acceptable medical practice would be to observe Mr. Pastor in the present setting of the coronary care unit for at least several more days to determine his clinical course and to provide for possible emergency treatment. I believe that participation in and attendance in his trial at this time as well as incarceration are injurious to his health and may have life threatening consequences.

Leslie A. Kuhn, M.D.
Director, Ames Coronary Care Unit
Associate Clinical Professor of Medicine

Sworn to before me this 19th
day of May, 1976

LAK/sgw

Notary Public, State of New York
No. 31-4536027
Qualified in New York County
Commission Expires March 30, 1977

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DOCKET ENTRIES

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
----------X

UNITED STATES OF AMERICA,

v. No. 76 Crim. 253

MARTIN WEINER, JUDGE MOTLEY

Defendant.
----------X

Proceedings

3-12-76	Filed indictment. Case assigned to Judge Motley superseding 75 Cr. 753. A Notice of Readiness has already been filed in 75 Cr. 753.
4- 1-76	A.M. . . Deft. & Atty. present. Pleads not guilty. Bail cont'd. $10,000 Pollack, J., as fixed in 75 Cr. 753. Trial adjd. to 5-17-76. . .Motley, J.
5-11-76	Filed opinion #44378. Defts. have presented the court with an omnibus motion which was filed on Jan. 5, 1976. The requests embodied in this more recent motion will be dealt with seriatim***The motion for recusal is accordingly denied. Motley, J. . . Mailed notice.
5-17-76	Filed court's exhibit 1 ordered sealed and placed in vault in cashier's office. Motley, J.
5-26-76	Filed Memorandum Opinion No. 44476. Defts. seek to dismiss motion and for reasons more fully set forth - The motion to dismiss the indictment is accordingly denied. Motley, J.
5-17	Jury selection is commenced.
5-18-76	Jury trial begun.
5-19-76	Jury trial cont'd.

5-20-76	Trial cont'd.
5-21-76	Trial cont'd.
5-24-76	Trial cont'd.
5-25-76	Trial cont'd.
5-26-76	Trial cont'd.
5-27-76	Trial cont'd.
5-28-76	Trial cont'd.
6- 1-76	Trial cont'd.
6- 2-76	Trial cont'd.
6- 3-76	Trial cont'd - Jury deliberations begun.
6- 4-76	Trial cont'd. & concluded. Deft. GUILTY on Cts. 1, 5 & 6. Unable to reach decision on Cts. 2, 3 & 4. Sent. adjd. to 7-26-76, 2 P.M. Deft's. bail cont'd. at $10,000 P.R.B. Court declares a mistrial on counts 2, 3 & 4. . .Motley, J.
6-10-76	Filed Govt's. requested voir dire of prospective jurors. Filed Govt's. memorandum of law in opposition to motions to dismiss for lack of venue.
6-25-76	Filed Govt's Requests to Charge.
6-25-76	Filed Deft's Requests to Charge.
7- 6-76	Filed Deft's Notice of Motion for an order directing the entry of a judgment of acquittal. RET: 7-26-76.
7-21-76	Filed Govt's Memorandum in opposition to deft's Post-Trial motions.
7-27-76	Filed Memo endorsed (on Notice of Motion dated: 7-6-76). . .The within post-trial motions of the deft. Martin Weiner for the setting aside of the deft's conviction by jury on counts 1, 5, and 6 or, in the alternative, for a new trial on said counts are hereby DENIED. So Ordered. Motley, J.

7-26-76	Filed Judgment #76715 (Atty. W. Donald Sparks present). Defendant sentenced to SIX (6) MONTHS on Counts 1, 5 & 6 to run concurrently with each other. Imposition of sentence is suspended. Defendant placed on probation for TWO (2) YEARS. Fine of $3,000.00 on Count 1 to be paid within 30 days for date (sic) of judgment. Defendant is to stand committed until the fine is paid, or he is otherwise discharged according to law. MOTLEY, J.
8- 3-76	Filed notice of appeal from judgment dated 7-26-76. Copy of U.S. Atty. and mailed to deft. c/o Met. Corr. Center, N.Y.C.
8-16-76	Filed Order -- That the imposition of the Three Thousand Dollar ($3,000.00) fine against deft. is stayed pending the disposition of the appeal. So ordered - MOTLEY, J.
9-15-76	Filed notice that the original record on appeal has been certified and transmitted to the U.S. C.A.
10-15-76	Filed transcript of record of proceedings dated 7-26-76.

BEST COPY AVAILABLE

4a

JUDGE XXXXXXX Assigned 0847

U.S. vs. PASTOR, EDWARD (LAST, FIRST, MIDDLE)

Case Filed Mo. 03 Day 12 Yr. 76 Docket No. 0253

No. of Defts. 02 JUVENILE

FELONY Fe x0208 1

U.S. MAG. CASE NO.

U.S. TITLE/SECTION	OFFENSES CHARGED	ORIGINAL COUNTS
21:846	Conspr. & distr. of Phentermine III.	1
21:843 (a)(3)	Possess. & contr. of Phentermine III by misrepresentation.	2-6

SUPERSEDING COUNTS

BAIL • RELEASE

Unsecured $ Set Date Conditions 10% Deposit Surety Bond Collateral 3rd Party Cust. Other

AMT Fugitive Pers. Recog FNSA

Bail Not Made Status Changed (See Docket)

II. KEY DATES & INTERVALS

ARREST	INDICTMENT X	ARRAIGNMENT	TRIAL	SENTENCE
U.S. Custody From 3-12-76	Information 3-12-76	1st Plea 4-1-76	Trial Begun 5-17-76	Disposition Hearing 6-4-76
Summons Served	Warrant Waived	Plea Filed	Trial Begun 5-18-76	9-17-76
First Appearance	In Charging District	Superseding Indict./Info.	Trial Ended 6-4-76	Convicted / On all Counts / Acquitted / On Lesser Offense(s) / Dismissed / VWOP / WP / On Government Motion

MAGISTRATE

Search Warrant Issued	Return	DATE	INITIAL/ND	INITIAL APPEARANCE DATE	INITIAL NO.	OUTCOME
Summons Issued	Served			PRELIMINARY EXAMINATION Date Scheduled / Date Held		DISMISSED / HELD FOR G.J. OR OTHER PROCEEDING IN THIS DISTRICT
Arrest Warrant Issued				REMOVAL HEARING		HELD FOR G.J. OR OTHER PROCEEDING IN DISTRICT BELOW
Complaint				WAIVER / INTERVENING INDICTMENT	Tape Number	
Offense in Complaint						

U.S. Attorney or Asst. ATTORNEYS Defense: CJA / Ret. / Ret. / Appointed / Public Defender / Pro Se / Other / Public Defender

John Timbers
791-1936

DATE	DOCUMENT NO.	PROCEEDINGS	EXCLUDABLE DELAY (a) (b) (c)
3-12-76		Filed indictment. Case assigned to Judge Motley superseding 75 Cr 753. A Notice of Readiness has already been filed in 75 Cr 753. Pollack, J.	
4-1-76		Atty.Andrew Cooper present..Deft not present Pleads not guilty bail cont'd. as previously fixed in 75Cr.753? trial adjd to 5-17-76..Motley,J.	
4-20-76		Filed affdvt. and notice of motion for an order to dismiss the original indictment and directing disclosure. Ret. 04-29-76 (filed in 75 Cr.753)	
4-20-76		Filed memorandum in support of omnibus motion. (filed in 75 Cr. 753)	
5--76		Filed Govts memorandum in opposition to omnibus pre-trial motion.	
5-6-76		Filed affdvt.of J.Timbers,AUSA in opposition to motion to adjourn trial.	
5-6-76		Filed opinion #44354..The motion of deft to post-pone the trial of this case now scheduled to commence on May 17,1976 is denied***In view of Mr. Pastor's heart condition and Mr.Kuh's condition the trial will be shortened to four hours per day.....So Ordered.....Motley,J. Mailed notice	
5-10-76		Filed order that Dr.M.Texon make examination of the deft,***is ordered that the U.S.Atty.pay a reasonable fee**Motley,J....	

3

	76Cr.253 CBM E.PASTOR	PAGE TWO	V. EXCLUDABLE DELAY
5-11-76	Filed application of Richard H.Kuh for reconsideration of Courts decision of May 6,1976 (Filed in 75Cr.753)		
05-11-76	Filed opinion # 44378 Defts have presented the court with an omnibus motion, which was filed on Jan.5-76. The requests embodied in this more recent motion will be dealt with seriatim.****The motion for recusal is accordingly denied.....Motley,J...mailed notice.....		
5-11-76	E.PASTOR - Filed memo endorsed on application of R.H.Kuh for reconsideration of decision of 5-6-76...The Court has reconsidered the request to postpone the trial and it is denied.....So ordered..Motley,J....m/n (Filed in 75Cr.753)		
5-13-76 ✓	P/T Conf. held & concluded..Suppression hearing adjd to 9a.m. 5-17-76 trial to commence after hearing.....Motley,J...		
5-14-76 ✓	Filed memorandum opinion #44410 By motion filed with the court on Jan.5-76 deft requested an order**appointing a physician***The Court finds,based on all the evidence that Mr.Pastor is able to withstand the stress of participation in a criminal trial and assist in his own defense, without grave risk to his life or health*****Motley,J...m/n		
5-14-76 ✓	Filed opinion # 44417 Deft by affdvt.of his counsel filed May 10,1975 asked this Court to reconsider its decision of May 6-76****The trial day has been reduced to four hours***The court sees no reason why such a reduced trial day should not meet the needs of this case***Motley,J.... m/n-----		
5-17-76	Filed Courts exhibit 1 ordered sealed, impounded and placed in vault in cashiers office.....Motley,J.		
5-19-76	Filed transcript of record of proceedings, dated 4-1-76.		
05-26-76	Filed a true copy of a order that the petition for a writ of mandamuas is denied.		
05-26-76	Filed Memorandum Opinion No. 44476. Defts seek to dismiss motion and for reasons more fully set forth - The motion to dismiss the indictment is, accordingly denied.MOTLEY,J m-n		
5-17-76	Jury selection commenced		
5-18-76	Jury trial begun..Bail is revoked & bench warrant is ordered. Motley,J.		
5-19-76	Trial cont'd.		
5-20-76	Trial cont'd.		
5-21-76	Trial cont'd.		
5-24-76	Trial cont'd.		
5-25-76	Trial cont'd.		
5-26-76	Trial cont'd.		
5-27-76	Trial cont'd.		
5-28-76	Trial cont'd.		
6-1-76	Trial cont'd.		
6-2-76	Trial cont'd.		
6-3-76	Trial cont'd. Jury deliberations begun		
6-4-76	Trial cont'd. & concluded..GUILTY on cts.1,5 & 6 unable to reach decision on Cts.2,3 & 4..Sent. adjd to 7-26-76 2 P.M. Bail set at $10,000 P.R.B. to be signed by deft and by wife. Court declares a mistrial on cts. 2,3 & 4.....Motley,J.		

FINE AND RESTITUTION PAYMENTS

CHECK NUMBER	CR NUMBER	DATE	RECEIPT NUMBER	CO NUMBER

See PAGE 3

DATE	PROCEEDINGS
6-4-76	E.PASTOR - Filed appearance bond in amt.of $10,000 co-signed by wife.
6-10-76	Filed Govts memorandum of law in opposition to defts motions to dismiss for lack venue
6-10-76	Filed govts memorandum in opposition to defts 2nd omnibus pre-trial motion
6-10-76	Filed Govts requested voir dire questions of prospective jurors
6-10-76	Filed notice of motion to dismiss the indictment...Recvd.in chambers 1-5-75..
6-10-76	Filed defts requests to voir dire
6-10-76	Filed Govts memorandum of law
6-10-76	Filed affdvt.of R.H.Kuh in support of request for an adjournment.
6-10-76	Filed defts memorandum in support of ommibus motion
6-25-76	Filed Govt's Requests to Charge.
6-25-76	Filed Deft's Requests to Charge.
7-1-76	Filed Deft's Affidavit, Notice of Motion and Memorandum of Law in support of an order setting aside the verdicts of guilty returned to deft on Count 1,5 & 6 of the indictment, etc. RET: 7-26-76.
7-20-76	Filed Remand(endorsement on back of MC, Deputy Clerk..Deft released from custody of U.S. Marshal..Bond posed as directed by the Court.
7-21-76	Filed Govt's Memorandum in opposition to defts' Post-Trial Motions.
7-26-76	HEARING HELD AND SENTENCING ADJOURNED TO SEPT. 1,1976, at 2PM,MOTLEY,
9-17-76	Filed Judgment(Atty.Robert Goldman,Present)Deft is committed for imprisonment for a period of SIX MONTHS on Ct.1 and FINED $5,000, sentenced to FOUR YEARS on each of Cts.5 & 6 to run concurrently with each other. Execution of sentence on Cts.5 and 6 are suspended. Deft is placed on probation for a period of FIVE YEARS, subject to the standing probation order of this Court...Sentence and fine imposed on ct.1 are stayed pending appeal, on condition that the appeal is promptly perfected within the time allowed by the rules. If the conviction is affirmed, the deft is to surrender within TEN DAYS after the affirmance...The fine of $5,000 is a committed fine and the deft is to stand committed until the fine is paid or he is otherwise discharged according to law.....The Court recommends that the deft be confined to an institution with appropriate medical facilities for his heart condition.....Motley,J.....Ent. 9-21-76.....
9-22-76	Filed memorandum opinion #45131 the purpose of this opinion is to set down in memorandum form the factual findings and legal conclusions encompassed in rulings made from the bench on two motions filed by deft.*****Defts motion for suppression of the identification testimony by Mr.Gallagher was denied....Motley,J...m/n
9-22-76	Filed notice of appeal from judgment of 9-17-76..copy given to U.S.Atty. and deft C/o Atty. Kuh,Shapiro,Goldman Cooperman & Levitt 600 3rd Ave. NYC

Felony ☐ Minor Offense ☐ Misdemeanor ☐

MAGISTRATE 0847 Disp./Sentence

0208 District | 1 Office

PASTOR, EDWARD — defendant — 7a

No. of Defdnts 02 *

74 76 0145

MAGR. CASE NO.

CHARGES	U.S. CODE SECTION	OFFENSES	COUNT
	21:846	Consp. to viol. Fed. Narco. Laws.	1
	21:843(a)(3)	Obtaining controlled substances by misrepresentation. Sch. III.	2-6

BAIL / RELEASE: ☐ Denied ☐ Personal R ☐ Unsecured AMT ☐ Conditional Rel Set (000) $ ☐ 10% ☐ Surety ☐ Collat ☐ 3rd P Cust ☐ PSA ☐ Bail Not Made ☐ Bail Status Changed (See Docket) Date

Defendant's Counsel: ☐ Retained ☐ Federal Defender ☐ CJA ☐ Waived ☐ Other

ATTORNEYS — U.S. Attorney: John Timbers, AUSA. (212) 791-1936

INTERVALS OF TIME BEFORE TRIAL

ARREST — U.S. Custody ☐ Bail/Other Conditions ☐ Date Charged ☐ High Risk Defendant

INDICTMENT ☒ Information ☐ 2-11-76 ☐ Waived ☐ Superseding ☐ In lieu of Info ☐

ARRAIGNMENT — 1st Plea ☐ Not Guilty ☐ Nolo ☐ Guilty — Trial Set For — Final Plea ☐ Not Guilty ☐ Nolo ☐ Guilty

TRIAL — Voir Dire ☐ — Trial Began ☐ J ☐ N — Trial Ended

Disposition — ☐ Convicted ☐ Acquitted ☐ Dismissed: ☐ Nolle/Discontinued ☐ On Motion of Govt ☐ On Motion of Defendant ☐ WOP:

SENTENCE

☐ Pre-sentence Investigation Ordered

		DATE	INITIAL/No.
Search Warrant	Issued		
	Return		
Summons	Issued		
	Served		
Arrest Warrant			
COMPLAINT ▷			
OFFENSE (In Complaint)			

INITIAL APPEARANCE — INITIAL/No.

PRELIMINARY EXAMINATION OR REMOVAL HEARING — Date Scheduled — Date Held — ☐ Waived ☐ Not Waived — ☐ Intervening Indictment

Tape No. — INITIAL/No.

OUTCOME — ☐ Dismissed ☐ Held for District Court — BOND ☐ Exonera ☐ To Trans District — ☐ Held to Answer to U. S. District Court — AT: — Magistrate's Initials ▷

MAGISTRATE

* Show last names and suffix numbers of other defendants on same indictment/information

V. Excludable Da (a) (b) (c

DATE — PROCEEDINGS — WEINER-2

DATE	PROCEEDINGS
2-11-76	Filed indictment. Assigned to Motley,J. as related to 75-753.
2-19-76	Filed order. The motion made by deft's to dismiss this superceding indictment is granted...Opinion follows... Motley,J.
2-20-76	Filed opinion #43906 deft s were originally indicted on July 31, 1975. Thereafter on 2-11-76 a new and different G.J. returned a superceding indictment*****the motion to dismiss the second indictment must be granted..As indicated.....Motley,J.

OPPOSITE THE APPLICABLE DOCKET ENTRIES IN SECTION IV SHOW, IN SECTION V, ANY OCCURRENCE OF EXCLUDABLE DELAY PER 18 USC §3161(h) — "SPEEDY TRIAL ACT"

CRIMINAL DOCKET
UNITED STATES DISTRICT COURT JUDGE MOTLEY

75 CRIM. 752

D. C. Form No. 100 Rev.

TITLE OF CASE	ATTORNEYS
THE UNITED STATES	For U.S.:
vs.	John Timbers, AUSA. 791-1984
[illegible] PASTOR	
[illegible] MEINER	
	For Defendant:
	H.Weiner - W.Donald Sparks,Esq Legal Arts Bldg.Front & Lemon Media,Pa. 19063
	E.PASTOR - Richard H.Kuh,Esq. 800 3rd Ave. NYC....

(07) STATISTICAL RECORD	COSTS		DATE	NAME OR RECEIPT NO.	REC.		DISB.	
J.S. 2 mailed	Clerk							
J.S. 3 mailed 12-2	Marshal							
Violation	Docket fee							
Title 21								
Sec. 846 & 843(a)(3)								
Consp. to viol. Fed. Narco. Laws.(Ct. 1) Obtaining controlled substances by misrepresentation. (Phendimetrazine,III.(Cts.2-5) (Five Counts)								

DATE	PROCEEDINGS
7-31-75	Filed indictment. B/W issued. B/W issued.
8-11-75	Deft.(atty. present) Pleads not guilty. Motions returnable in 10 days Deft. ordered photographed and fingerprinted. Deft. R.O.R. Case assigned to Judge Motley for all purposes. Stewart,J.
8-12-75	MARTIN MEINER Filed notice of appearance by W.Donald Sparks Legal Arts Bldg. Front & Lemon Media, Pa.
8-12-75	EDWARD PASTOR - Filed notice of appearance by Richard H.Kuh 800 3rd Ave. NYC Tel.688-7000....
11-7-75	Filed opinion #43359 defts have moved to compel the Govt, to produce all statements purportedly made by the defts.the Govt. is ordered to produce any and all materials to which defts are entitled under the provisions of amended Rule 16... Motley, J....n/m
11-19-75	Filed Govt's bill of particulars.
12-3-75	BOTH DEFTS - Filed Govt's notice of readiness for trial..

-OVER-

DATE	PROCEEDINGS
-5-76	E.PASTOR - Filed affdvt.and notice of motion for an order dismissing the indictment. To suppress any statements..For discovery and for bill of particulars..Ret. Jan. 30-76
-5-76	E.PASTOR - Filed memorandum in support of omnibus motion.
-6-76	M.WEINER - Filed affdvt. notice of motion for an order dismissing the indictment, to inspect Grand Jury minutes, for Discovery and inspection, for bill of particulars etc....
-27-76	Filed Govt's memorandum in opposition to defts omnibus pre-trial motion.
1-27-76	Filed affdvt of William W.Vodra,Associate Chief Counsel for FDA
-29-76	Filed envelope ~~containing~~ containing a letter and affidavit ordered sealed and placed in clerks vault.....Motley,J.
2-2-76	Filed memo endorsed on letter dtd.1-30-76....Pltff will have until 2-3-76 to reply So Ordered....Motley,J...
2-2-76	Filed order that affdvt. and covering letter executed by AUSA J.TIMBERS be sealed. Motley,J.....
2-3-76	~~Filed reply affdvt in support of motion~~ Ent. in error
2-3-76	E.PASTOR - Filed reply affdvt.of R.H.Kuh in reply to W.W.Vodra and J.Timbers...
2-13-76	Filed Govt's affdvt.& ~~xxx~~ Order to show cause for an order permitting the Govt. to inspect and copy etc.. Ret. 2-13-76 at 3:30 P.M. Room 506....Motley,J.....
2-13-76	EDWARD PASTOR - Filed order that Dr.Meyer Texon examin deft to determine defts physical ability to stand trial***the U.S.ATTY. is directed to pay reasonable fee not to exceed $250.00.....Motley,J....
2-19-76	Filed Govt's supplemental bill of particulars..
2-76	Filed Govt's notice of motion for an order rescheduling trial date....Memo endorsed. Motion to advance the date of trial denied.....Motley,J....m/n
3-20-76	EDWARD PASTOR-- filed affdvt. and notice of motion for an order to dismiss the original indictment and directing disclosure. Ret. 04-29-76 (also filed in 76 Cr.253)
3-20-76	EDWARD PASTOR-- Filed memorandum in support of omnibus motion. (also filed in 76 Cr. 253)
4-28-76	E.PASTOR - Filed stip. and order that all motions made in respect to the original indictment***be deemed to be made and submitted in respect to the superseding indictment...
4-30-76	MARTIN WEINER - Filed notice of motion for an order allowing deft to incorporate by reference portions of omnibus motion filed by co-deft...Ret.5-10-76....
4-30-76	E.PASTOR - Filed affdvt.& notice of motion for an order adjourning the trial of this case and pre-trial hearings...Ret.5-5-76...

— See Page 3 —

75 CR 753 3c 10a MOTLEY, J.

DATE	PROCEEDINGS
5-6-76	Filed stip.and order that all particulars,statements etc. be deemed to be produced with respect to the original indictment....Motley, J.
[illegible]-75	Filed transcript of record of proceedings dated Feb.18,1976
05-11-76	EDWARD PASTOR Filed application of Richard H.Kuh for reconsideration of Courts decision of May 6
5-13-76	E.PASTOR - Filed memo endorsed on application of R.H.Kuh for reconsideration of decision of 5-6-76....The Court has reconsidered the request to postpone the trial and it is denied.....So ordered Motley,J....m/n
6-4-76	PASTOR-WEINER-Filed transcript of record of proceedings dated 10-15-7
6-8-76	EDWARD PASTOR) MARTIN WEINER) Filed order of dismissal..The U.S.Atty.having moved to dismiss the instant indictment***the instant indictment is dismissed....Motley,J....
6-10-76	E.PASTOR - Filed in Court(2-23-76) order to show cause directing a hearing be held concerning identifications etc.
6-10-76	Filed affdvt.of John Timbers,AUSA in opposition to omnibus pre-trial motion.
8-20-76	Filed transcript of [illegible] dated 9-22-75, 5-13, 17, 18, 19, 20, 21-76
	Filed transcript of [illegible] dated 5-24, 25, 5-26, 5-27 76
	Filed [illegible] 5-28-76, 6-1, 6-2, 6-3, 6-4-76

D. C. 109 Criminal Continuation Sheet

INDICTMENT

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
----------X
UNITED STATES OF AMERICA,

v.

No. 76 Crim. 253

EDWARD PASTOR and MARTIN WEINER,

Defendants.
----------X

COUNT ONE

The Grand Jury charges:

1. From on or about the 1st day of March, 1973, and continuously thereafter up to and including the date of the filing of this indictment, in the Southern District of New York and elsewhere, EDWARD PASTOR and MARTIN WEINER, the defendants, Charles Fernald and Douglas Berry, named herein as co-conspirators but not as defendants, and others to the Grand Jury unknown, unlawfully, intentionally and knowingly combined, conspired, confederated and agreed together and with each other to violate Sections 812, 841(a)(1), 843(a)(2) and 843(a)(3) of Title 21, United States Code.

Objects of the Conspiracy

2. It was part of said conspiracy that the said defendants unlawfully, intentionally and knowingly would, in the course of the distribution of Schedule III and IV controlled substances, use a registration number which was suspended

and issued to another person in violation of Sections 812 and 843(a)(2) of Title 21, United States Code.

3. It was further part of said conspiracy that the said defendants unlawfully, intentionally and knowingly would by misrepresentation, fraud, forgery, deception and subterfuge acquire and obtain possession of Schedule III and IV controlled substances, in violation of Sections 812 and 843(a)(3) of Title 21, United States Code.

4. It was further part of said conspiracy that the said defendants unlawfully, intentionally and knowingly would distribute and possess with intent to distribute Schedule III and IV controlled substances, the exact amounts thereof being to the Grand Jury unknown, in violation of Sections 812 and 8431(a)(1) of Title 21, United States Code.

The Means by Which the
Conspiracy Was Carried Out

5. Among the means by which the defendants and their co-conspirators would and did carry out the conspiracy were the following:

(a) The defendants, EDWARD PASTOR and MARTIN WEINER, did order and receive from co-conspirator Charles Fernald, a broker engaged in the business of distributing drugs, phendimetrazine and phentermine which are respectively Schedule III and Schedule IV controlled substances under the federal narcotics law.

(b) The defendants, EDWARD PASTOR and MARTIN WEINER, were not registered with the Federal Drug Enforcement Administration, or its predecessors, to purchase phendimetrazine and phentermine although, as these defendants well knew, only persons so registered could legally purchase phendimetrazine and phentermine. In an attempt to evade this requirement of the law the defendants, PASTOR and WEINER, falsely represented to co-conspirator Charles Fernald and others that they were ordering the phendimetrazine and phentermine for a Dr. Horace Johnson, who, they falsely represented, was a physician registered with the Drug Enforcement Administration, and its predecessors, to receive phendimetrazine and phentermine.

(c) Through the use of forged documents and other fraudulent means, the defendants, EDWARD PASTOR and MARTIN WEINER, did order and receive more than five million phendimetrazine and phentermine tablets and capsules.

OVERT ACTS

In pursuance of the said conspiracy and to effect the objects thereof, the following overt acts were committed in the Southern District of New York, and elsewhere:

1. In or about May, 1973, EDWARD PASTOR, the defendant, told Charles Fernald that, when PASTOR ordered drugs, PASTOR did not want invoices sent to PASTOR or to Doctor Horace Johnson.

2. On or about June 22, 1973, MARTIN WEINER, the defendant, paid Charles Fernald $4,475.00 in cash and received

800,000 phendimetrazine tablets in Manhattan, New York.

3. In or about June, 1973, MARTIN WEINER, the defendant, told Charles Fernald, over the telephone, that the 800,000 phendimetrazine tablets that WEINER had ordered from Fernald were intended for a doctor.

4. In or about September, 1973, EDWARD PASTOR, the defendant, told Charles Fernald that the 250,000 phendimetrazine capsules that PASTOR was ordering were intended for Dr. Horace Johnson.

5. In or about October, 1973, EDWARD PASTOR, the defendant, ordered one million phendimetrazine capsules for Doctor Horace Johnson.

6. On or about November 23, 1973, EDWARD PASTOR, the defendant, caused the signature of Dr. Horace Johnson to be forged on a letter that purported to be confirmation of an order for phendimetrazine capsules.

7. In or about 1974, at the APA Transport terminal in Philadelphia, Pennsylvania, EDWARD PASTOR, the defendant, falsesly stated to an employee of APA Transport that PASTOR was Doctor Horace Johnson.

8. In or about April, 1974, EDWARD PASTOR, the defendant, ordered one million phentermine tablets for Doctor Horace Johnson from Charles Fernald.

9. In or about April 18, 1974, EDWARD PASTOR, the defendant, caused the signature of Dr. Horace Johnson to be

forged on a letter that purported to be an order by Doctor Horace Johnson for one million phentermine tablets.

(Title 21, United States Code, Section 846.)

COUNT TWO

The Grand Jury further charges:

In or about July, 1973, in the Southern District of New York, EDWARD PASTOR and MARTIN WEINER, the defendants, unlawfully, intentionally and knowingly did obtain possession of Schedule III controlled substances, to wit, approximately 100,000 phendimetrazine capsules, by misrepresentation, fraud, deception, and subterfuge.

(Title 21, United States Code, Section 843[a][3] and Title 18, United States Code, Section 2.)

COUNT THREE

The Grand Jury further charges:

In or about August, 1973, in the Southern District of New York, EDWARD PASTOR and MARTIN WEINER, the defendants, unlawfully, intentionally and knowingly did obtain possession of Schedule III controlled substances, to wit, approximately 2,000,000 phendimetrazine tablets, by misrepresentation, fraud, deception, and subterfuge.

(Title 21, United States Code, Section 843[a][3] and Title 18, United States Code, Section 2.)

COUNT FOUR

The Grand Jury further charges:

In or about September and October, 1973, in the Southern District of New York, EDWARD PASTOR and MARTIN WEINER, the defendants, unlawfully, intentionally and knowingly did obtain possession of Schedule III controlled substances, to wit, approximately 250,000 phendimetrazine capsules, by misrepresentation, fraud, deception, and subterfuge.

(Title 21, United States Code, Section 843[a][3] and Title 18, United States Code, Section 2.)

COUNT FIVE

The Grand Jury further charges:

From October, 1973 up to and including June, 1974, in the Southern District of New York, EDWARD PASTOR and MARTIN WEINER, the defendants, unlawfully, intentionally and knowingly did obtain possession of Schedule IV controlled substances, to wit, approximately 1, 080,000 tablets of phentermine, by misrepresentation, fraud, forgery, deception, and subterfuge.

(Title 21, United States Code, Section 843[a][3] and Title 18, United States Code, Section 2.)

/s/ Robert B. Fiske, Jr.
ROBERT B. FISKE, JR.
United States Attorney

/s/ James McBride
FOREMAN

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

- -X

UNITED STATES OF AMERICA,

Plaintiff,

-against-

EDWARD PASTOR and MARTIN WEINER,

Defendants.

- -X

NOTICE OF MOTION

75 Crim. 753 (CBM)

S I R S : -

PLEASE TAKE NOTICE, that upon the annexed affidavit of Richard H. Kuh, sworn to on the 2nd day of January, 1976, and the exhibits annexed to such affidavit, the indictment herein, and all the proceedings heretofore had herein, the defendant, EDWARD PASTOR, will move this Court, at a term thereof to be held before the Honorable CONSTANCE BAKER MOTLEY, Judge of the United States District Court for the Southern District of New York, at a part thereof to be held at the United States Courthouse, Foley Square, in the Southern District of New York, on the 30th day of January, 1976, at 9:30 o'clock in the forenoon of that day, or as soon thereafter as counsel can be heard for an Order:

(1) Pursuant to Rule 12 of the Federal Rules of Criminal Procedure dismissing the indictment, and each count thereof, against the defendant, EDWARD PASTOR, upon the following grounds:

June 25-73 Pltf's memorandum
July 10-73 Pltf's memorandum

A. The said indictment and each of its counts do not state facts sufficient to constitute an offense against the United States, in that they allege as crimes certain purported acts that were not rendered criminal by Act of Congress, but rather by Rule of the prosecutor, the Attorney General of the United States, in derogation of the Constitution of the United States, specifically the provisions of the Constitution lodging all legislative powers in the Congress (Article I, Section 1) and the "due process" clause, Amendment V; and

B. The said indictment and each of its counts do not state facts sufficient to constitute an offense against the United States, in that they allege as crimes certain purported acts denominated as criminal by the prosecutor, the Attorney General of the United States, pursuant to standards that were unconstitutionally vague, and in an abusive exercise of his discretion, without an adequate basis in law or in fact for the said criminalization of such acts.

(2) Pursuant to Rule 12 of the Federal Rules of Criminal Procedure dismissing the said indictment and each of its counts, because this Court is without jurisdiction, in that none of the crimes charged in the indictment are cognizable in this district, none of the acts of the defendants and the purported co-conspirators (named but not indicted) allegedly taken to effect any of the elements of said crimes having taken place in the Southern District of New York.

(3) Pursuant to Rule 12(b)(3) of the Federal Rules of Criminal Procedure, and Miranda v. Arizona, 384 U.S.436, 16 L.Ed. 694 (1966), and other federal decisions,

directing the suppression of any statements purported to be made by the defendant, EDWARD PASTOR, and prohibiting the use by the United States Government in evidence of such statements, because of the violation of defendant's rights under the Fifth and Sixth Amendments of the Constitution of the United States, or directing that a hearing be held on the voluntariness of any statements, purportedly made by the defendant, EDWARD PASTOR, that the United States Government intends to use, should there be a trial in this matter.

(4) Pursuant to Brady v. Maryland, 373 U.S. 83, 10 L.Ed.2d 215 (1963), and other federal decisions, ordering that prompt discovery be granted by the Government of the United States to the defendant, EDWARD PASTOR, of all material now known to the Government, or which may become known, or which through due diligence may be learned from the investigating agents, the Drug Enforcement Administration, or the witnesses in the case, which is or may be exculpatory in nature, or favorable to the defendant, or which may lead to exculpatory material, to include but not limited to:

A. The names and addresses and grand jury testimony of such persons, if any, who testified before the grand jury who will not be called by the Government at trial;

B. The names and addresses of all persons who have been interviewed by agents of the United States in connection with the subject matter of this case and whom the Government does not presently intend to call at trial, and the statements, if written or recorded, of those persons, or if no written or recorded statements exist, a summary of each of the statements made;

C. All documents, of any kind and description, obtained by the Government from any sources outside the Government in the course of this investigation which the Government does not presently intend to use at the trial of this matter;

D. All documents and information of any kind whatsoever, if any, in derogation of the fitness of Dr. Horace Johnson to practice medicine, to be authorized to prescribe and dispense and obtain narcotic drugs or other substances controlled by federal or state law;

E. The criminal records, if any, of all persons the Government intends to call at trial, specifically to include but not limited to Dr. Horace Johnson, Charles Fernald and Douglas Berry; the recorded statements, if any, made by any agent of the United States (including personnel of the United States' Attorney's office) at or in connection with the sentencing of each such person; the agreements, if any, each such person has or had with any agent of the United States concerning cooperation with the United States in criminal matters and investigations; any promise of non-prosecution or any immunity grant ever made to any such person, and if a grant of immunity was made, all Government documents pertaining to such grant; the gravamen of any statements made by any agent of the United States (including personnel of the United States' Attorney's office) to any representative of the Probation Department of any federal or state court in connection with such sentencing; any Federal Bureau of Investigation or Drug Enforcement Agency or any other Governmental agencies' report on any of the purportedly criminal activities of such person including criminal activities for which such person was never formally charged, and without regard to whether or not the proof was adequate to support a

criminal charge; any threats of prosecution or of any punitive activity, whether direct or indirect, ever conveyed to any such person by any Government agent; any mental hospitalization or other mental history of any kind or degree, known to or ascertainable by the Government concerning such person; any falsehoods ever alleged by such person whether or not under oath, to any agent of any federal or state Government at any time whether or not such false statements were recorded or made in writing; any other information concerning any such person that may be in derogation of his honesty or capacity to accurately observe or report; and

F. All statements of all persons the Government intends to call at trial, specifically to include but not limited to Dr. Horace Johnson, Charles Fernald and Douglas Berry, insofar as any portions of said statements differ with the anticipated testimony of each such person, whether made in the grand jury or otherwise, and insofar as any of such statements were not written or recorded, a summary of each of such statement.

(5) Pursuant to Rule 16 of the Federal Rules of Criminal Procedure ordering prompt discovery be granted by the Government of the United States to the defendant EDWARD PASTOR of the following items:

A. Pursuant to Rule 16(a)(1)(A), the defendant's written or recorded statements, and the substance of his oral statements, to the extent directed by the Rule and not yet furnished, if any;

B. Pursuant to Rule 16(a)(1)(B), the defendant's prior criminal record, if any;

C. Pursuant to Rule 16(a)(1)(C), all books, papers, documents, photographs, tangible objects or copies of portions thereof, which are within the possession, custody or control of the Government, which may be material to the preparation of the defense, or which are intended for use by the Government at the trial; this is to include, but is not limited to, those items that are:

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1. Purportedly reflective of any falsehood perpetrated in any way by either of the defendants, or the purported unindicted co-conspirators, or Dr. Horace Johnson, in connection with the alleged use of the name Dr. Horace Johnson, or any credentials of the said Dr. Johnson, in connection with the ordering, possession, receiving or disposing of controlled substances, and is to include but is not limited to all documents reflective of Dr. Johnson's status at all relevant times with regard to controlled substances;

2. Purportedly reflective of any of the activities of the unindicted co-conspirators, Fernald and Berry, or personnel employed with or by each such co-conspirator, bearing on any of the transactions reflected in the indictment;

3. Purportedly reflective of long distance telephone calls among the defendants and the purported co-conspirators, and other persons with whom they were allegedly in contact with for criminal purposes; and

4. Those documents received by the United States Attorney from the Drug Enforcement Administration, in compliance with the defense requests of September 22, 1975 and October 15, 1975, and the Court's directions of those dates, retained by the prosecutor as set forth in ¶12 of the moving Kuh affidavit.

D. Pursuant to Rule 16(a)(1)(D) all results or reports of examinations and of scientific tests, if any, copies of which are within the possession, custody, or control of the Government which may be material to the preparation of the defense are or intended for use by the Government at the trial.

(6) Pursuant to Rule 7(f) of the Federal Rules of Criminal Procedure ordering the Government of the United States to file a further bill particularizing the

following matters embraced within the indictment, not hitherto supplied, as without such matters the defendant cannot adequately and properly prepare for trial:

A. Any and all overt acts not enumerated in the first count of the indictment concerning which the Government intends to offer evidence upon trial;

B. If the Government intends to offer evidence of false and fraudulent pretenses or representations not specifically set forth in the indictment, provide the substance thereof;

C. Those facts upon which the Government expects to reply to show that the federal court in the Southern District of New York has jurisdiction over the subject matter of the indictment, and each count thereof;

D. As to the conspiracy count (the first count) of the indictment:

1. State the date and circumstances under which each purported conspirator (the defendants and the unindicted co-conspirators) purportedly joined the conspiracy as alleged in the first paragraph of the said count;

2. State the registration number or numbers purportedly utilized by the defendants, the date and circumstances of the purported suspension of such number or numbers, the person or persons to whom each such number had been issued, and the specific means of the purported violations of §§812 and 841 (a)(2) of Title 21 of the United States Code, as alleged in the second paragraph of the said count;

3. State the specific means of the purported violations of §§812 and 843 (a)(3) of Title 21 of the United States Code, as alleged in the third paragraph of the said count;

4. State the dates, places, times and persons who allegedly distributed or possessed the controlled substances unlawfully, and the specific means of the purported violations of §§812 and 841 (a)(1)of Title 21 of the United States Code, as alleged in the fourth paragraph of the said count;

5. State the times, places and amounts of the orders and receipts, and the persons involved with the controlled substances, as alleged in paragraph 5(a) of the said count;

6. State the times and places of the representations purportedly made by the defendants that they were acting for Dr. Horace Johnson, and if specific documents are relied upon set forth or make available for copying each such document, as alleged in paragraph 5(b) of the said first count;

7. Set forth the fraudulent means purportedly utilized by the defendants, and if specific documents are relied upon set forth or make available for copying each such document, as alleged in paragraph 5(c) of the said first count;

8. As to overtact "1", alleged in the said first count, state whether other persons were present at such conversation, and if so name such other persons and specify the instructions purportedly given by Pastor to Fernald;

9. As to overt act "2", alleged in the said count, state whether other persons were present, the means used for payment, and the present whereabouts, if known, of the funds thus described;

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10. As to overt act "3", alleged in the said first count, state precisely what Weiner allegedly stated to Fernald, where Weiner was at the time of the purported conversation, and whether other persons were present at such conversation, and if so name such other persons;

11. As to overt act "4", alleged in the said first count, state whether other persons were present at such conversation, and if so name such other persons;

12. As to overt act "5" alleged in the said first count, if the said order was purportedly in writing, set forth or make available for copying such document;

13. As to overt act "6" alleged in the said first count, state precisely the means used by Pastor to cause the said forgery, and set forth or make available for copying such document;

14. As to overt act "7", alleged in the said first count, state the names and addresses of all employees to whom the said Pastor purportedly falsely stated that he was Dr. Horace Johnson, the dates of such statements, whether other persons were present when such statements were made, and if so, name such other persons, and if any of the said statements was in writing set forth or make available for copying such documents;

15. As to overt act "8", alleged in the said first count, state precisely where Pastor was at the time of the purported conversation, where it took place, and whether other persons were present at such conversation, and if so name such other persons, and if the order was in writing set forth or make available for copying such document;

16. As to overt act "9", alleged in the said first count, state precisely how Pastor purportedly caused the said forgery, where it took place, and set forth or make available for copying such document.

(7) Pursuant to Alderman v. United States, 395 U.S. 165, 182, 22 L.Ed.2d 176, 192, rehearing denied 394 U.S. 939, 22 L.Ed.2d 475 (1969), ordering the Government to produce:

A. All records of any electronic eavesdropping, or applications for same, which occurred at the home or place of business of either of the defendants or of the unindicted co-conspirators, or at any other place or places, which eavesdropping was intended to audit conversations of either of the defendants or of anyone for those actions the defendants are charged with criminal responsibility whether in the Southern District or elsewhere, whether by the United States Attorney, the Drug Enforcement Administration, or any other personnel of the United States Government;

B. Any mail or other correspondence sent to the defendants or to the purported unindicted co-conspirators, through the United States Postal System or otherwise, that has been intercepted or otherwise, inspected by Government personnel.

(8) Pursuant to United States v.Cannone, ____ F.2d _____(2d Cir. 1975), 18 Cr. L. Rep. 2103, October 29, 1975, and United States v. Holmes, ____ F.2d ____ (D.C. Cir. 1975), 18 Cr. L. Rep. 2199, December 13, 1975, ordering the Government to produce the names and addresses of any persons who actively participated

in the investigation (whether as witnesses, investigators or otherwise) of matters of which the derendant stands accused, and who are expected to testify for the Government at the trial.

(9) Pursuant to United States v. Knohl, 379 F.2d 427, 434-37 (2d Cir.), cert. den. 389 U.S. 973, 19 L. Ed. 2d 465 (1967), appointing a physician or physicians to examine the defendant, EDWARD PASTOR, to advise the Court and counsel with regard to continuing the trial of the instant indictment as to the said defendant until such time as a trial of that indictment will not present a danger to said defendant's health or will not endanger the said defendant's life, and until such time as the said defendant will be able to properly assist in his own defense, or ordering a hearing concerning such continuance.

(10) All other and further relief as to this Court may seem just and proper, including the scheduling of the furnishing of 3500 materials, and including reservation to the defense of the right to make such further

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pre-trial motions, if any, as may be appropriate in light of such discovery and other relief as is granted on the instant motion.

Dated: New York, New York
January 2, 1976

Yours, etc.

KUH, SHAPIRO, GOLDMAN, COOPERMAN
& LEVITT, P.C.
Attorneys for the Defendant
Edward Pastor
Office & P. O. Address
800 Third Avenue
New York, New York

By Richard H. Kuh
RICHARD H. KUH, PARTNER

TO:

HON. THOMAS J. CAHILL
United States Attorney
Southern District of New York
United States Courthouse
Foley Square
New York, New York

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

- -X

UNITED STATES OF AMERICA,

Plaintiff,

-against-

EDWARD PASTOR and MARTIN WEINER,

Defendants.

- -X

AFFIDAVIT IN SUPPORT OF OMNIBUS MOTION

75 Crim. 753 (CBM)

STATE OF NEW YORK)
COUNTY OF NEW YORK) SS.:

RICHARD H. KUH, being duly sworn, deposes and says:

1. I am a partner in the law firm of Kuh, Shapiro, Goldman, Cooperman & Levitt, P.C., retained by the defendant, Edward Pastor, to represent him in the above indicated action.

2. I submit this affidavit in support of the omnibus motion, made on behalf of Edward Pastor, seeking a dismissal of the indictment as against him on various grounds or, should dismissal not be ordered, a hearing on the use in evidence of statements purportedly made by Pastor, and various items of discovery, all as set forth in the Notice of Motion.

3. Edward Pastor is presently engaged in, and I am informed has long been engaged in, the retail drug business in the Philadelphia, Pennsylvania, area where he resides. I

am informed that there are a chain of Pastor's Pharmacies with which he is connected and that he also is active in a large mail order pharmaceutical business, one selling prescription drugs at cut rates to members of unions and other sizeable organizations.

4. The instant indictment charges Mr. Pastor, in five counts, with purported criminal violations arising from transactions involving phentermine and phendimetrazine, neither of which were listed as controlled substances in any of the schedules found in 21 U.S.C. §812, as that section was enacted by the Congress. See 21 U.S.C.A. §812. Both of these substances are, I am informed, primarily weight reducing drugs. Each, however, was added to the schedules of controlled substances by action of the Attorney General in mid-1973, the Attorney General purportedly acting pursuant to authority contained in 21 U.S.C. §811.

5. The Notice of Motion to which this affidavit is appended sets forth the various items of relief sought in this omnibus motion. Only those items that require factual support extrinsic to the indictment itself are considered in this affidavit, and so some of the items covered in the Notice of Motion - such as item 1.A. thereof - are not dealt with in this affidavit.

The Attorney General's Action
In Classifying Phentermine and
Phendimetrazine As Controlled Drugs
(Item 1.B., Notice of Motion;
Point II, Law Memorandum).

6. Initially at a pre-trial conference held on September 22,1975, and then at a second such conference on October 15, 1975, the Court ordered the Government to turn over to defense counsel certain materials relied upon by the Attorney General in classifying the drugs phendimetrazine and phentermine. The deadline set by thr Court at the second such conference was November 1, 1975.

7. Subsequent to that conference, defense counsel was notified by Assistant United States Attorney John Timbers, that we should communicate with Richard I. Lebovitz, Esq., of the Office of the Chief Counsel of the Drug Enforcement Administration (formerly the Bureau of Narcotics and Dangerous Drugs), concerning the materials we desired. We indicated we would do so, to facilitate the United States Attorney's production, but that it was the prosecutor to whom we looked for such timely production. Thereafter, on October 17, 1975, we (my associate at this law firm, Andrew R. Cooper and I) spoke by telephone with Mr. Lebovitz and specified the aforementioned materials. On the same date we sent a letter, a copy of which is appended as Exhibit "A" to this affidavit, to Mr. Lebovitz confirming our requests.

8. On or about November 21, 1975 -- some three weeks subsequent to the November 1, 1975 production deadline -- we were notified by the Government that materials were available, and we received those items shortly thereafter.

9. On or about December 9,1975 -- more than five weeks after the date for production, as set forth in conference -- we were notifed by the Government that additional materials, covered by our request but not earlier delivered, were available. Those materials were delivered on December 12, 1975.

10. On or about December 18, 1975 -- almost seven weeks after the deadline -- we were notified by the Government that still more materials earlier requested were available. We received those additional materials on December 19, 1975.

11. In a letter dated December 22, 1975 and received December 26, 1975, a copy of which is appended as Exhibit "B" to this affidavit, Mr.Timbers stated "that the documents you received last Friday complete the DEA's response to your request for documents that is incorporated in Mr. Cooper's October 17, 1975 letter to Mr. Lebovitz."

12. In a telephone conversation, on or about December 24, 1975, Mr. Timbers asserted that we were in possession of all "relevant" documents requested. Upon Mr. Cooper's asking

Mr. Timbers if there were any documents which he received from the Drug Enforcement Administration in compliance with our request, but that he did not turn over to us, even at that late date, he replied affirmatively. Mr. Timbers stated that certain materials prepared by Government agencies pursuant to our request of October 17, 1975 were not turned over, including, among other items, a bibliography indexing certain scientific and related literature concerning phentermine. We do not understand this gamesmanship, and submit that it is unworthy of the United States Government, and ask that the assistant prosecutor be direcred to turn over all documents he received from the Drug Enforcement Administration.

13. Except for approximately 1,000 pages of scientific articles and related literature, (the indexing of which the prosecution has apparently withheld), we have read through all of the materials received from the Government totalling almost 3,800 pages. The remainder of this affidavit, except where otherwise indicated, is based upon these materials.

14. On February 15, 1973, in a letter from Richard L. Seggel, Acting Assistant Secretary for Health to John E. Ingersoll, Director of the Bureau of Narcotics and Dangerous Drugs (B.N.D.D.), the office of the Secretary of the Department of Health, Education and Welfare (H.E.W.) recommended that

phendimetrazine and phentermine, among other drugs, be placed in Schedule III of the Controlled Substances Act. By notice dated May 1, 1973 (hereinafter referred to as the "proposal date"), and appearing in the Federal Register, Volume 38, pages 12126 through 12130, appended as Exhibit "C" to this affidavit, John E. Ingersoll, as Director of B.N.D.D. proposed that phendimetrazine and phentermine be placed in Schedule III of the Controlled Substances Act.

15. Apparently "no objections nor requests presenting reasonable grounds for a hearing" (according to Mr. Ingersoll) concerning phendimetrazine were received and by order dated June 12, 1973, published in the Federal Register on June 15, 1973, Volume 38, pages 15719 through 15722, and appended as Exhibit "D" to this affidavit, phendimettazine was placed in Schedule III.

16. An objection and request for a hearing -- apparently deemed "reasonable" -- regarding the proposed order on phentermine was filed on May 21, 1973,and supplemented on June 11, 1973, by Pennwalt Corporation. In light of those objections and requests for a hearing, a final order controlling phentermine was not included in the June 12, 1973 order. See Exhibit "D".

17. By order dated June 29, 1973 and appearing in the Federal Register on July 6, 1973, Volume 38, pages 18013

through 18015, appended as Exhibit "E" to this affidavit, an order was issued placing phentermine in Schedule IV in the interim before hearings could be held(and before a final order might be issued on the proposal to place phentermine in Schedule III).

18. In the Federal Register of October 15, 1973, Volume 38, page 28579, appended as Exhibit "F" to this affidavit, notice was given that a hearing concerning the scheduling of phentermine would commence on October 31, 1973. Pre-hearing conferences were held on November 9 and December 10, 1973.

19. In a telephone conversation in early November, 1975 with James M. Johnstone, Esq., attorney for Pennwalt Corporation, we were informed that final hearings regarding the proposal to place phentermine in Schedule III were never held. We were further informed that phentermine was continued in Schedule IV with the understanding that that placement would be evaluated over a period of approximately 18 months.

20. Although (as above in ¶17), phentermine had become a Schedule IV controlled substance on July 6, 1973, and its scheduling had been proposed on May 1, 1973 (as above, in ¶14), after it became apparent that hearings on phentermine would be necessary, the B.N.D.D. began to prepare for those

hearings. In the course of those preparations, for the most part subsequent to the proposal for scheduling and even to the inclusion of the drug on Schedule IV, a great deal of purported evidence was amassed. The results of that effort are evidenced by the quantity of material we received concerning phentermine as opposed to that received concerning phendimetrazine. Out of close to 3,800 pages of material we received, some 600 pages relate to phendimetrazine and approximately 3,200 pages relate to phentermine. In addition, as above, a great quantity of the material received is dated after the drugs were proposed for scheduling and even placed in the schedules in May, June and July 1973, up to and including November 6, 1975. Therefore, these materials could not have been considered in deciding whether, or in which schedule, to place the drugs. There is also much material which, although dated before the proposal and scheduling dates, was obviously not considered until after the drugs were proposed to be scheduled, and even scheduled, since it was apparently received as a result of searches done after the order in preparation for the scheduled phentermine hearings. Approximately three-fourths of the phentermine materials and one-half of the phendimetrazine materials could not have been relied upon in proposing the drugs for scheduling.

21. The materials received that could have been

relied upon contain no index, and, for the most part, there is no indication as to when any of them was placed into the files of B.N.D.D. or the Drug EnforcementAdministration. There is nothing to indicate what portion of these materials was actually relied upon in determining that the two drugs should be proposed for scheduling.

22. Phendimetrazine -- the materials turned over relating to phendimetrazine were received in ten separate packets, all except #4 marked "Phendimetrazine" and all except #1 containing a general subject label on the first page:

> a. Packet #1 is unlabelled. Of the twenty-four documents in the packet, eight are dated after the proposal date for the drug. The remaining data, for the most part, consists of correspondence and memoranda concerning some specific instances of alleged phendimetrazine abuse and crime laboratory identification of the drug. Included are a memorandum, appended as Exhibit "G" to this affidavit, dated October 27, 1972, concluding that there is not sufficient information to control the drug and that there is very little street abuse, and recommending, among other things, that "if the drug must be scheduled now - add more weight to less important scheduling factors"; and another memorandum, appended as Exhibit "H" to this affidavit, dated August 28, 1972, reaching the same conclusion and recommendations, following a preliminary literature review.
>
> b. Packet #2 is labelled "Literature - Searches". It consists of two searches performed on March 10, 1975, by the National Library of Medicine's Remote - Access Retrieval Service, at the request if a Dr. Zendzian. Only citations and very brief statements as to content are given.

c. Packet #3 is labelled "GFT". Approximately three-fifths of the materials are dated after the proposal date. The remaining material consists of responses of Government agents to requests by superiors to legitimately obtain samples of phendimetrazine.

d. Packet #4 is labelled "Anorectic Drugs, Greensboro, N.C. - GFT". It consists of the results of two surveys, both done after the proposal date. The first, requested on February 21, 1974, regards the abuse of anorectics, and the second, requested on June 25, 1973, regards investigation and registration of firms handling anorectic drugs. Also included is a list of documents, prepared October 28, 1975 or later.

e. Packet #5 is labeled "Patent". It contains two patent specifications, relating to the Production of Substantial Tetrahydro-1, 4-Oxazines, and to the Production of Substituted Tetrahydrooxazines. It is not apparent how either of these specifications relates to phendimetrazine.

f. Packet #6 is labelled "Marketing Data". It contains a list of drug codes, prepared under the auspices of "Project Label", on December 9 and 10, 1974. It also contains marketing data on numerous drugs, including samples of magazine advertising, which have no apparent relationship to the guidelines set forth in 21 U.S.C. §811(c).

g. Packet #7 is labelled "Compliance". It consists of a progress report of a grant to the Texas Department of Public Safety which contains, in addition to some information about other drugs, two notations of investigations of phendimetrazine diversion in 1972. A duplicate of this report is found in phentermine packet #5, apparently transmitted to B.N.D.D. along with other materials in June and July 1973. It is likely, therefore, that though the report is dated January 18, 1973, it was not received or considered before the proposal date.

h. Packet #8 is labelled "Lab Reports, Ballistics Case Reports". Approximately one-third of the material is dated after the proposal and scheduling dates. It consists of reports of laboratory analyses of drugs, including phendimetrazine, obtained by various law enforcement

agencies.

i. Packet #9 is labelled "Detection in body fluids". It consists of a scientific article published in a periodical dated June, 1975.

j. Packet #10 is labelled "(Plegine, et al.)." It consists of copies of notices published in the Federal Register, duplicates of much of the compliance material in packet #7, correspondence with Ayerst Laboratories, a manufacturer of phendimetrazine, including a letter from Ayerst stating that it would not object to the proposed scheduling, and some additional documentation of specific instances of phendimetrazine abuse.

23. Nowhere in the phendimetrazine materials is there a single, specific finding concerning any of the eight factors contained in 21 U.S.C. §811(c).

24. Phentermine -- the materials turned over relating to phentermine were received in twenty-two separate packets, all except #1, 2, 17 and 18 marked "Phentermine", and all except #1, 2, 4, 5, 6 and 17 containing a general subject label on the first page:

a. Packet #1 is unlabelled. All of the material is dated after the proposal date. It contains correspondence and documents relating to the request of Pennwalt Corporation for a hearing regarding phentermine, and minutes of pre-hearing conferences, the cover page and relevant pages containing some of the Hearing Judge's remarks appended as Exhibit "V" hereto. Included is a letter from Pennwalt, appended as Exhibit "I" to this affidavit, dated June 8, 1973, citing the following grounds on which Pennwalt objected to the findings made in the proposal to schedule phentermine:

"1. The findings are erroneous as a matter of fact as not being in accord with the weight of the scientific evidence available with respect to phentermine.

//

"2. The findings are erroneous as a matter of law.

"3. The Director, in the proposed scheduling for phentermine, and fenfluramine, has failed to apply the appropriate standards for phentermine and fenfluramine in determining their proposed scheduling."

b. Packet #2 is unlabelled. It is a duplicate of packet #1.

c. Packet #3 is labelled "Compliance Survey Theft Reports". Approximately one-half of the material is dated after the proposal date. It contains the results of a survey regarding the availability and abuse of Ionamin (the trade name under which Pennwalt markets phentermine), conducted in July-August, 1973 and dated September 10, 1973; results of a similar survey dated June 21, 1973; results of a survey of theft data requested June 3, 1974, and dated June 24, 1974; a general informational bulletin setting up procedures to be followed, issued prior to the proposal date and possibly not relevant in that it is identical to a memorandum in packet #15 of the phentermine materials, which was not received until June 12, 1973; results of surveys conducted in June and July, 1973, in response to requests to document phentermine abuse; a memorandum of a meeting held on September 5 1973 to discuss changing the then existing drug scheduling procedures; copies of Federal Register notices and related documents; a memorandum, appended as Exhibit "J" to this affidavit, dated January 10, 1973, discussing, among other things, the relative manpower demands different scheduling would require; and the letter from H.E.W. recommending scheduling, with accompanying review material sent by H.E.W. to B.N.D.D. The review material just referred to consists of summary tables and bibliographies compiled by the Food and Drug Administration drug abuse staff on data relevant to the abuse potential of anorectic drugs.

d. Packet #4 is unlabelled. Approximately one-fifth of the material is dated after the proposal date. It consists of memoranda and letters

documenting the extensive preparation and investigation undertaken after the proposal to schedule phentermine was made and the need for hearings was realized; a memorandum, appended as Exhibit "K" to this affidavit, dated March 13,1973, of a meeting to coordinate B.N.D.D.'s response to H.E.W.'s control recommendation of several anorectics, documenting several unwarranted and irrelevant considerations relied upon in scheduling those drugs; memoranda and related documents, appended as Exhibits "L" and "M" to this affidavit, dated in the autumn of 1972, documenting certain scientifc data collected, including reports that listed phentermine as having a low abuse potential rating and creating only mild psychic dependence, and concluding either that documentation of the abuse of phentermine is wanting, Exhibit "L", or that a recommendation to control phentermine cannot be made, Exhibit "M"; and additional compliance lab reports and crime reports.

e. Packet #5 is unlabelled. All of the material is dated after the proposal date. It consists of documentation of the extensive preparations being undertaken for the phentermine hearings.

f. Packet #6 is unlabelled. It consists of correspondence with Pennwalt subsequent to the proposal date.

g. Packet #7 is labelled "Synthesis". It consists of a report on the chemistry of phentermine prepared on October 25, 1973, and reprints of scientific materials apparently attached to that report.

h. Packet #8 is labelled "GFT". It contains compliance reports, all dated in 1974.

i. Packet #9 is labelled "Marketing Data". It consists of a list of drug codes, prepared under the auspices of "Project Label", on December 9 and 10, 1974. It also contains other marketing data, including copies of actual labels of phentermine as it is marketed.

j. Packet #10 is labelled "FDA inhouse Philosophy of Control". It consists of internal memoranda within the Department of Health, Education and Welfare. There is no indication that any of this material was ever transmitted to or received by B.N.D.D. Included is a memorandum, appended as Exhibit "N" to this affidavit, dated December 20, 1972, explaining the insufficiency of the guidelines established by Congress in 21 U.S.C. §811(c).

k. Packet #11 is labelled "Dawn Data". It consists of a report, dated May 7, 1974, "prepared by the Project Dawn Scientific Investigators regarding selected drug substances."

l. Packet #12 is labelled "Federal Register Notices". It consists of Federal Register notices, indexed on November 6, 1975.

m. Packet #13 is labelled "(Ionamin, Wilpo)". Approximately three-fifths of the material is dated after the proposal date. The post-proposal date material includes responses to surveys requesting information, memoranda dated July 24, 1973 and August 16, 1973 detailing efforts to contact drug dependence treatment centers, and correspondence with Pennwalt Corporation. The pre-proposal date material includes reports of phentermine abuse and crime statistics, and the same letter and review materials from H.E.W. contained in packet #3.

n. Packet #14 is labelled "Recommendation of SEC. of HEW Schedule III 2/15/73". It contains the same letter and review materials from H.E.W. contained in packets #3 and #13.

o. Packet #15 is labelled "Compliance Survey Theft Reports". The reports were indexed on November 6, 1975 and all but one were received after the proposal date.

p. Packet #16 is labelled "Lab Analysis & Ballistics Case Reports". Approximately four-fifths of the material is dated after the proposal date. It consists largely of computer printouts, processed on July 25, November 6 and December 7, 1973 and January 11, 1974, of past laboratory analyses relating to phentermine. The pre-proposal date materials contain a few instances of reports by law enforcement agencies of cases involving phentermine.

q. Packet #17 is unlabelled. With the possible exception of one page out of approximately 250, all of the materials are dated or apparently received after the proposal date. They relate to information concerning the possibility of phentermine abuse in West Germany, including by members of the United States military.

r. Packet #18 is labelled "References/ miscellaneous". It consists of copies of scientific articles,some of which relate directly to phentermine, some indirectly, and others not at all. The list of references includes articles published as recently as May, 1975. The more recent articles are not all collected at the beginning or end of the packet, but are interpersed throughout.

s. Packet #19 is labelled "Literature Searches". It consists of two bibliographical citation lists of scientific articles compiled by the National Library of Medicine's Remote - Access Retrieval Service on March 10, 1975 in response to a request by Dr. Zendzian. Also included is a list of references to phentermine in Chemical Abstracts, apparently accumulated in a literature search done in August 1972, but without any explanatory remarks.

t. Packet #20 is labelled "Literature A-E". It consists merely of a bibliography of scientific articles apparently relating to phentermine and other anorectic drugs, including references to articles published after the proposal date. None of the articles referred to are reprinted.

u. Packets #21, #22 and #23 are labelled "Literature F-L", "Literature M-P", and "Literature R-Z", respectively. They consist of copies of scientific articles apparently relating to phentermine and other anorectic drugs. Of the seventy-two articles reprinted, about one-fifth were published after the proposal date. The remaining date back as far as 1940. The articles published after the proposal date are interspersed throughout the materials.

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25. Nowhere in the phentermine materials is there a single, specific finding concerning any of the eight factors contained in 21 U.S.C. §811(c)*

The Lack of Venue In the Southern District of New York (Item 2, Notice of Motion).

26. In a pre-trial conference on October 15, 1975, the Court indicated that our lack if venue contention probably could not be decided in advance of trial.

27. Pursuant to that indication, and though the issue is included in the Notice of Motion to ensure its preservation, no legal argument is included in the Law Memorandum; we submit most respectfully that the Court should reserve decision at this time on this venue point.

Suppression of Pastor's Statements For Violation Of His Constitutional Rights (Item 3, Notice of Motion; Point III, Law Memorandum).

28. Appended hereto as Exhibits "O" and "P" are the

* Sheer bulk inhibits the physical annexation to this affidavit of the multiple packets of phendimetrazine and phentermine materials received from the Drug Enforcement Administration. At the argument of this omnibus motion, the material will be tendered to the Court. For purposes of this motion we respectfully request that they be deemed part of the motion papers.

reports of Drug Enforcement Agent V. na of his interviews with Edward Pastor on December 9th, 1974 and February 26th, 1975 respectively. A purported -- but woefully incomplete -- transcript of the February 26, 1975 interview is appended as Exhibit "Q". As will be seen from the Vigna summary, the December 9th, 1974 interview was conducted after Pastor had been subpoenaed to appear before a grand jury but had telephoned to indicate that he was entering the hospital on December 10, 1974.

29. Although both of Vigna's interview summaries allege that "Vigna ... advised EDWARD PASTOR of his rights," I am informed that he, Edward Pastor, has no recollection of having received such advice and that his belief is that no such advice was given in the course of either interview. I note from my reading of the transcript of the February 26, 1975 interview that not only does it, as incomplete as it is, cover far broader ground than is indicated in the Vigna report (suggesting some highly subjective choices by Vigna in terms of what to report and what not to report), but there is not a word in that transcript seemingly reflective of any warning, or advice to Pastor of his rights, or of any waiver by Pastor of those rights. Moreover, there is no accounting for the lack of a transcript of the December 9, 1974 interview.

30. Appended hereto as Exhibits "R" and "S" are letters (dated September 25, 1975 and November 6, 1975) re-

ceived by counsel from Dr. Gaddo Onesti, Professor of Medicine at the Hahnemann Medical College and Hospital, and the specialist treating Mr. Pastor for his extremely serious heart condition. These letters not only reveal the severity of that ailment, but show that Mr. Pastor has been under daily sedation since October 1972, and hence was under such sedation at the time of the two interviews conducted by Agent Vigna. As Dr. Onesti notes, the combination of these drugs "result very frequently in loss of mental alertness, drowsiness, disorientation and mental confusion." Possibly because of these factors -- or quite possibly because, in fact, no warnings had been given -- I am satisfied from my own conversations with Mr. Pastor that there was no knowledgeable waiver on his part of his Constitutional rights at the time of his interviews by the federal agent.

31. I further understand that Mr. Pastor, as someone engaged in the lawful retailing of drugs in the Philadelphia area, when requested by an agent of the Drug Enforcement Administration to appear for an interview believed he had no practical choice but to appear and to submit to questioning. I am advised that Mr. Pastor appeared without counsel, and without seeking the advice of counsel, in each instance. As more fully considered in the accompanying Law Memorandum, we respectfully submit that the use on trial of Mr. Pastor's statements would be improper, these interviews having been con-

ducted in derogation of his Constitutional rights and without any knowledgeable or intelligent waiver of them; we further submit that at such hearing as this Court may order, under the circumstances the Government will not be able to establish any knowledgeable or intelligent waiver by Mr. Pastor of his Constitutional rights.

Brady Materials (Item 4, Notice of Motion; Point IV, Law Memorandum).

32. After meeting informally with the Assistant United States Attorney to whom this case is assigned, under date of September 26, 1975 I wrote to that prosecutor requesting that the Government make discovery materials, including Brady materials, available to the defense without the need for any formal motion. Appended hereto as Exhibit "T" is a copy of the response we received from the United States Attorney's office; we particularly call the Court's attention to the first two paragraphs of the second page thereof in connection with Brady materials. Because the Government has not yet made any such items available, this formal motion for them has been made, and the legal grounds have been developed in the Memorandum of Law submitted herewith.*

* Item 5 of the Notice of Motion, dealing with discovery, requires no extrinsic factual support.

The Request for a Bill of Particulars (Item 6, Notice of Motion).

33. The Government has voluntarily provided a Bill of Particulars in this case, which we received on November 20, 1975. The items requested in the Notice of Motion cover particulars not provided in the Bill of Particulars already received.

The Production of Electronic Eavesdropping and Mail Surveillance Data (Item 7, Notice of Motion, Point V Law Memorandum).

34. In a letter dated September 22, 1975, appended hereto as Exhibit "U", Mr. Timbers states:

> "During our discussion I informed you that the Government did not utilize any electronic surveillance or wiretap in connection with this case. In addition, I undertook to determine whether the Drug Enforcement Administration or United States Attorney's Offices in Manhattan or Philadelphia, Pennsylvania have used electronic surveillance or wiretap on your clients in any connection; ..."

35. We have not been advised of the results of Mr. Timbers' undertaking with respect to the Drug Enforcement Administration or the United States Attorney's Offices in Manhattan or Philadelphia. Neither have we been advised as to any mail or correspondence interception by the Government or any of its agencies.*

* Item 8 of the Notice of Motion, considering a witness list, requires no extrinsic factual support.

Continuance Because of Edward Pastor's Health (Item 9, Notice of Motion; Point VI, Law Memorandum).

36. As earlier stated, we have appended hereto as Exhibits "R" and "S" two letters received from Dr. Gaddo Onesti, the specialist treating Edward Pastor for his grave heart ailments.

37. From my own personal observations, premised upon several conferences with Edward Pastor, I add my own serious doubts as to his ability to assist effectively in his own defense. Apparently because of the medication that he is and has been taking, Mr. Pastor has appeared to me to be less than alert, and with less than the normal ability to recall, without confusion, past events.

38. No previous application has been made for the relief sought herein, other than that, informally, at a conference with the Court and the prosecutor some discovery questions had been discussed and discovery had been unsuccessfully sought at that time of statements purportedly made by Pastor to alleged co-conspirators.

WHEREFORE, it is respectfully submitted that the relief sought herein be granted, together with such other relief as this Court may deem just and proper.

Sworn to before me this
2nd day of January, 1976

Evelyn Kay

EVELYN KAY
Notary Public, State of New York
No. 41-0552230 Qual. in Queens Co.
Commission Expires March 30, 1977

Richard H. Kuh

RICHARD H. KUH

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October 17, 1975

Richard Ira Lebovitz, Esq.
Room 1203F
Office of Chief Counsel
D.E.A.
1405 "I" Street, N.W.
Washington, D.C. 20537

Re: United States v. Pastor and Weiner

Dear Mr. Lebovitz:

It was a pleasure for Richard H. Kuh and me to speak with you this afternoon. This letter will confirm the requests we made to you at that time. As we stated, these requests are made pursuant to (i) a conference held before the Honorable Constance B. Motley, and (ii) The Freedom Information Act.

The items which we request, in all respects, refer to the drugs phendimetrazine and phentermine. They are as follows:

1. The Attorney General's request, if any, to the Secretary of Health, Education and Welfare, is a scientific and medical evaluation, and recommendations as to whether each drug or substance should be controlled.

2. The report of the Secretary of Health, Education and Welfare, and any accompanying documentation.

a. All underlying data on which that report was based, including, but not limited to:

(i) any reports of advisory or other designated committees, used, relied upon, prepared for, or presented to the Secretary or his designee, and accompanying documentation;

(ii) reports or materials presented by drug companies or other interested parties, and accompanying documentation;

(iii) any and all findings made and materials relied upon as to each of the following considerations:

(1) the drug's actual or relative potential for abuse;

(2) scientific evidence of its pharmacological effect, if known;

(3) the state of current scientific knowledge regarding the drug;

(4) its history and current pattern of abuse;

(5) the scope, duration and significance of abuse;

(6) what, if any, risk there is to the public health;

(7) its psychic or psychological dependence liability;

(8) whether the substance is an immediate precursor of a substance already controlled.

(iv) any and all findings and materials relied upon as to the items enumerated in 21 U.S.C. § 812 (b)(3) and (4), respectively;

(v) any and all factors considered in recommending the appropriate schedule on which to place each drug;

(vi) any other material submitted by the Secretary to the Attorney General.

3. Any and all reports, evidence, or other materials submitted to the Attorney General.

a. All underlying data on which those reports, evidence or materials were based;

b. Any and all findings made and materials relied upon by the Attorney General as to each of the considerations enumerated in 2.a., iii, (1)through(8), inclusive, above.

4. Any and all notices of relevant proposals and rules that were made, including, but not limited to:

a. Publication in the Federal Register, with dates;

b. Inclusion in other Government publications, with dates;

c. Notices to the Trade in any other form, with dates.

5. With respect to phendimetrazine, the following materials reviewed by the Bureau of Narcotics and Dangerous Drugs, as stated at 38 Federal Register, 12,126-12,127:

a. Material referred to in, and attached to, the letter from Richard L. Seggel to John E. Ingersoll;

b. Material submitted to the Food and Drug Admi istration in connection with new drug applications, including those applications;

c. Publication of scientific and medical literature from the United States and other nations;

d. Selected investigatory files compiled for law enforcement purposes by the Bureau and other law enforcement agencies;

(i) the names of any such agencies.

e. The legislative history of the Controlled Substances Act.

6. With respect to phentermine, the following materials reviewed by the Bureau of Narcotics and Dangerous Drugs, as stated at 38 Federal Register, 12,127-12,129:

a. same as 5.a., above, through 5.e., above.

7. Any and all comments or objections, and supplements thereto, to the proposed rules which were received, and any and all responses or actions taken as a result.

8. The Hearing Minutes, and any and all materials relied upon, presented, or otherwise used during the Hearing of October 31, 1973, referred to in Notice of Hearing, 38 Federal Register, 28,579.

9. Any and all documents concerning the history of the dr[illegible] subsequent to their becoming controlled substanc[illegible]s, relating to reconsider[illegible]on, reclassification or declassification of their controlled substance or respective schedu[illegible] status.

I understand that if any of the requested items are unavailable, or if you are otherwise unable to secure them, you will so advise us.

Thank you for your cooperation in this matter.

Very truly yours,

Andrew R. Cooper

ARC:meb

Andrew R. Cooper

cc John Timbers, Esq.
Assistant United States Attorney

cc W. Donald Sparks, Esq.

Unmed States Department of Justice

UNITED STATES ATTORNEY
SOUTHERN DISTRICT OF NEW YORK
UNITED STATES COURTHOUSE
FOLEY SQUARE
NEW YORK, N. Y. 10007

55a

U. S. ATTORNEY'S OFFICE
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ADDRESS REPLY TO
"UNITED STATES ATTORNEY"
AND REFER TO
INITIALS AND NUMBER

JT:js

75-2637

December 22, 1975

Richard H. Kuh, Esq.
Kuh, Shapiro, Goldman, Cooperman & Levitt, P.C.
800 Third Avenue
New York, New York 10022

Re: United States v. Pastor and Weiner
75 Cr. 753 (CBM)

Dear Mr. Kuh:

I understand through Andrew Cooper, Esq. of your office that last Friday you received copies of Drug Enforcement Administration ("D.E.A.") orders, hearing transcripts and CFR Notices concerning the 1973 rescheduling of phentermine. These materials were recently forwarded to me by the D.E.A. as supplements to documents previously produced in this case.

I understand from Richard Lebovitz, Esq. of the D.E.A. Office of Chief Counsel, that the documents you received last Friday complete the D.E.A.'s response to your request for documents that is incorporated in Mr. Cooper's October 17, 1975 letter to Mr. Lebovitz.

Very truly yours,

THOMAS J. CAHILL
United States Attorney

By: John Timbers
JOHN TIMBERS
Assistant United States Attorney
Telephone: (212) 791-1984

cc: Honorable Constance Baker Motley
United States District Judge
United States Courthouse
Foley Square
New York, New York 10007

W. Donald Sparks, Esq.
Legal Arts Building
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[21 CFR Part 308]

SCHEDULES OF CONTROLLED SUBSTANCES

Proposed Placement of Phendimetrazine in Schedule III

On February 15, 1973, the Acting Assistant Secretary for Health, on behalf of the Secretary of Health, Education, and Welfare, sent the following letter to the Director of the Bureau of Narcotics and Dangerous Drugs:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

OFFICE OF THE SECRETARY

Washington, D.C. 20201

FEBRUARY 15, 1973.

JOHN E. INGERSOLL,
Director, Bureau of Narcotics and Dangerous Drugs, eDpartment of Justice, 1405 I Street NW., Washington, D.C. 20537

DEAR MR. INGERSOLL: The Food and Drug Administration has recently completed a review of all drugs currently marketed or proposed for marketing in the United States for the treatment of obesity. The marketed drugs include three substances already controlled under schedule II of the Controlled Substances Act, amphetamine, methamphetamine, and phenmetrazine. The review also included drugs currently not controlled under any schedule, the marketed drugs, diethylpropion, benzphetamine, phendimetrazine, phentermine, and chlorphentermine, and the investigational substances, clortermine, mazindol, and fenfluramine. New drug applications have been submitted to the Food and Drug Administration for the latter three drugs, and approval is pending.

Review of data reveals that these drugs produce approximately the same degree of therapeutic effects in man as currently scheduled anorectics, as adjuncts in weight reduction in the obese. The review indicated that the drugs are also comparable in other ways to scheduled anorectics:

a. They are all closely related chemically, with the exception of mazindol.

b. Their pharmacological profiles are closely similar, except for certain aspects of the profile of fenfluramine.

c. Documentation of actual abuse or production of dependence in humans is irregular, but does exist for certain of the unscheduled anorectics. The skimpy documentation of abuse of these drugs appears due to the fortuitous nature of reports as currently obtained and to the past easy availability of cheaper and more potent stimulants, rather than to intrinsic lack of abuse potential.

d. We note the conclusions and recommendations of the WHO Expert Committee on Drug Dependence that these drugs either be subject to control or by analogy are similar to drugs recommended for control.

e. Certain specialized testing of fenfluramine suggests that the abuse potential of fenfluramine is of a lower order of magnitude than that of the other drugs under consideration.

We, therefore, conclude that all the above-named drugs possess abuse potential and potential for producing drug dependence, and are so informing you as required under the provisions of section 201(f) of the Controlled Substances Act. As provided for by section 201(a), we further request that the Attorney General issue rules adding the above drugs to the schedules of the Controlled Substances Act, and recommend that the schedule for all drugs but fenfluramine be schedule III, fenfluramine appearing more appropriately controlled under the provisions of schedule IV.

We attach review material assembled by reviewing pharmacologists within the Food and Drug Administration for its possible utility to you, and as a basis for further discussion after your scientists have reviewed our recommendations and request.

Sincerely,

RICHARD L. SEGGEL,
Acting Assistant Secretary for Health.

Upon receipt of this letter, the Bureau undertook a review of the following: (1) Materials submitted to BNDD by the Department of Health, Education, and Welfare with the letter of February 15, 1973; (2) materials submitted to the Food and Drug Administration in connection with new drug applications on these drugs; (3) published scientific and medical literature from the United States and other nations regarding these drugs; (4) selected investigatory files compiled for law enforcement purposes by the Bureau and another law enforcement agency; and (5) the legislative history of the Controlled Substances Act.

The results of this review can be summarized as follows:

(1) Phendimetrazine is chemically similar to and related to the other anorectic drugs being proposed for control, and to amphetamine, methamphetamine, and phenmetrazine, substances currently listed in schedule II.

(2) Phendimetrazine has a pharmacological profile which is similar to the other anorectic drugs being proposed for control and to amphetamine, methamphetamine, and phenmetrazine. This general similarity suggests that all of these drugs may be reasonably substituted for each other for therapeutic or abuse purposes.

(3) Phendimetrazine is covered by a new drug application approved by the Food and Drug Administration for use in treatment of obesity.

(4) Products containing benzphetamine, chlorphentermine, diethylpropion, phendimetrazine, or phentermine have been marketed in the United States for several years. In the last 6 months, certain of these products have been reported as the subject of thefts, diversion, illicit sales, and abuse. Quantitatively, this data does not suggest a widespread problem at the present time; qualitatively, the data indicates a trend to substitute these products for amphetamine and methamphetamine preparations in abuse circles. This reinforces the belief that abuse of the pharmacologically similar drugs will increase as the amphetamines and methamphetamine become less and less available.

(5) The legislative history of the Controlled Substances Act makes clear that the Bureau is to schedule drugs based upon their potential for abuse, and "should not be required to wait until a number of lives have been destroyed or substantial problems have arisen before designating a drug as subject to controls." (Comprensive Drug Abuse Prevention and Control Act of 1970, H. Rept. 91-1444 (pt. 1), p. 35, Sept. 10, 1970.) Discussing factors used to measure potential for abuse, the report quotes from the regulations issued under the Drug Abuse Control Amendments of 1965 (id. at p. 34):

"The Director may determine that a substance has a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect if:

"(1) There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals of the community; or

"(2) There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or

"(3) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice."

The House report goes on to say (id. at p. 35):

"In speaking of 'substantial' potential [for abuse] the term 'substantial' means more than a mere scintilla of isolated abuse, but less than a preponderance. Therefore, documentation that, say, several hundred thousand dosage units of a drug have been diverted would be 'substantial' evidence of abuse despite the fact that tens of millions of dosage units of that drug are legitimately used in the same time period."

The Director has concluded from this review of the current situation that control of all anorectic drugs is desirable at this time to insure that they will not become widely abused. This scheduling will fulfill the congressional mandate to act before substantial problems have arisen.

Based upon the investigations and review of the Bureau of Narcotics and Dangerous Drugs and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to sections 201 (a) and (b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811 (a), (b)), the Director of the Bureau of Narcotics and Dangerous Drugs finds that:

1. Based on information now available, phendimetrazine has a potential for abuse less than the drugs or other substances currently listed in schedule II. Although chemically and pharmacologically this drug is closely related to the other anorectic drugs being proposed for control and to the stimulants now listed in schedule II, present data regarding excessive usage, diversion, illicit sales, and abuse of phendimetrazine is not substantial enough to warrant a finding that it has a potential for abuse equal to the stimulants in schedule II.

2. Phendimetrazine has a currently accepted medical use in treatment in the United States.

3. Abuse of phendimetrazine may lead to high psychological dependence.

Therefore, under the authority vested in the Attorney General by section 201(a) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a)), and delegated to the Director of the Bureau of Narcotics and Dangerous Drugs by § 0.100 of title 28 of the Code of Federal Regulations, the Director proposes that § 308.13 of title 21 of the Code of Federal Regulations be amended to read:

§ 308.13 Schedule III.

* * * * *

(b) *Stimulants*.—Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in schedule II which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under § 308.32, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances	1405
(2) Phendimetrazine	1620

* * * * *

Conferences have been held between the Bureau and the Ayerst Laboratories Division of the American Home Products Corp., the largest manufacturer of phendimetrazine in the United States and the only firm with a new drug application for phendimetrazine approved by the Food and Drug Administration. Ayerst Laboratories has fully cooperated with the Bureau and has consented to the placement of phendimetrazine in schedule III to insure that it does not become subject to abuse in the future.

All other interested persons are invited to submit their comments or objections in writing regarding this proposal. These comments or objections should state with particularity the issues concerning which the person desires to be heard. Comments and objections should be submitted in quintuplicate to the Hearing Clerk, Office of Chief Counsel, Bureau of Narcotics and Dangerous Drugs, Department of Justice, room 611, 1405 I Street NW., Washington, D.C. 20537, and must be received no later than June 7, 1973.

In the event that an interested party submits objections to this proposal which present reasonable grounds for this rule not to be finalized and requests a hearing in accordance with 21 CFR 308.45, the party will be notified by registered mail that a hearing on these objections will be held at 10 a.m. on June 11, 1973, in room 1210, 1405 I Street, NW., Washington, D.C. 20537. If objections submitted do not present such reasonable grounds, the party will be so advised by registered mail.

If no objections presenting reasonable grounds for a hearing on the proposal are received within the time limitations, and all interested parties waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Director may cancel the hearing and, after giving consideration to written comments, issue his final order pursuant to 21 CFR § 308.48 without a hearing.

Dated May 1, 1973.

JOHN E. INGERSOLL,
Director, Bureau of Narcotics and Dangerous Drugs.

[FR Doc.73-9069 Filed 5-8-73;8:45 am]

[21 CFR Part 308]

SCHEDULES OF CONTROLLED SUBSTANCES

Proposed Placement of Phentermine in Schedule III

On February 15, 1973, the Acting Assistant Secretary for Health, on behalf of the Secretary of Health, Education, and Welfare, sent the following letter to the Director of the Bureau of Narcotics and Dangerous Drugs:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

OFFICE OF THE SECRETARY

Washington, D.C. 20201

FEBRUARY 15, 1973.

JOHN E. INGERSOLL,
Director, Bureau of Narcotics and Dangerous Drugs, Department of Justice, 1405 I Street NW., Washington, D.C. 20537

DEAR MR. INGERSOLL: The Food and Drug Administration has recently completed a review of all drugs currently marketed or proposed for marketing in the United States for the treatment of obesity. The marketed drugs include three substances already controlled under schedule II of the Controlled Substances Act, amphetamine, methamphetamine, and phenmetrazine. The review also included drugs currently not controlled under any schedule, the marketed drugs, diethylpropion, benzphetamine, phendimetrazine, phentermine, and chlorphentermine, and the investigational substances, clortermine, mazindol, and fenfluramine. New drug applications have been submitted to the Food and Drug Administration for the latter three drugs, and approval is pending.

Review of data reveals that these drugs produce approximately the same degree of therapeutic effects in man as currently scheduled anorectics, as adjuncts in weight reduction in the obese. The review indicated that the drugs are also comparable in other ways to scheduled anorectics:

a. They are all closely related chemically, with the exception of mazindol.

b. Their pharmacological profiles are closely similar, except for certain aspects of the profile of fenfluramine.

c. Documentation of actual abuse or production of dependence in humans is irregular, but does exist for certain of the unscheduled anorectics. The skimpy documentation of abuse of these drugs appears due to the fortuitous nature of reports as currently obtained and to the past easy availability of cheaper and more potent stimulants, rather than to intrinsic lack of abuse potential.

d. We note the conclusions and recommendations of the WHO Expert Committee on Drug Dependence that these drugs either be subject to control or by analogy are similar to drugs recommended for control.

e. Certain specialized testing of fenfluramine suggests that the abuse potential of fenfluramine is of a lower order of magnitude than that of the other drugs under consideration.

We, therefore, conclude that all the above named drugs possess abuse potential and potential for producing drug dependence, and are so informing you as required under the provisions of section 201(*l*) of the Controlled Substances Act. As provided for by section 201(a), we further request that the Attorney General issue rules adding the above drugs to the schedules of the Controlled Substances Act, and recommend that the schedule for all drugs but fenfluramine be schedule III, fenfluramine appearing more appropriately controlled under the provisions of schedule IV.

We attach review material assembled by reviewing pharmacologists within the Food and Drug Administration for its possible utility to you, and as a basis for further discussion after your scientists have reviewed our recommendations and request.

Sincerely,

RICHARD L. SEGGEL,
Acting Assistant Secretary for Health.

Upon receipt of this letter, the Bureau undertook a review of the following: (1) Materials submitted to BNDD by the Department of Health, Education, and Welfare with the letter of February 15, 1973; (2) materials submitted to the Food and Drug Administration in connection with new drug applications on these drugs; (3) published scientific and medical literature from the United States and other nations regarding these drugs; (4) selected investigatory files compiled for law enforcement purposes by the Bureau and another law enforcement agency; and (5) the legislative history of the Controlled Substances Act.

The results of this review can be summarized as follows:

(1) Phentermine is chemically similar to and related to the other anorectic drugs being proposed for control, and to amphetamine, methamphetamine, and phenmetrazine, substances currently listed in schedule II.

(2) Phentermine has a pharmacological profile which is similar to the other anorectic drugs being proposed for control and to amphetamine, methamphetamine, and phenmetrazine. This general similarity suggests that all of these drugs may be reasonably substituted for each other for therapeutic or abuse purposes.

(3) Phentermine is covered by a new drug application approved by the Food and Drug Administration for use in treatment of obesity.

(4) Products containing benzphetamine, chlorphentermine, diethylpropion, phendimetrazine, or phentermine have been marketed in the United States for several years. In the last 6 months, certain of these products have been reported as the subject of thefts, diversion, illicit sales, and abuse. Quantitatively, this data does not suggest a widespread problem at the present time; qualitatively, the data indicates a trend to substitute these products for amphetamine and methamphetamine preparations in abuse circles. This reinforces the belief that abuse of the pharmacologically similar drugs will increase as the amphetamines and methamphetamine become less and less available.

(5) The legislative history of the Controlled Substances Act makes clear that the Bureau is to schedule drugs based upon their potential for abuse, and "should not be required to wait until a number of lives have been destroyed or substantial problems have arisen before designating a drug as subject to controls." (Comprehensive Drug Abuse Prevention and Control Act of 1970, House Report 91-1444 (part 1), p. 35, Sept. 10,

1970.) Discussing factors used to measure potential for abuse, the report quotes from the regulations issued under the Drug Abuse Control Amendments of 1965 (id. at p. 34):

> The Director may determine that a substance has a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect if:
>
> (1) There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community; or
>
> (2) There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or
>
> (3) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice.

The House report goes on to say (id. at p. 35):

> In speaking of "substantial" potential [for abuse] the term "substantial" means more than a mere scintilla of isolated abuse, but less than a preponderance. Therefore, documentation that, say, several hundred thousand dosage units of a drug have been diverted would be "substantial" evidence of abuse despite the fact that tens of millions of dosage units of that drug are legitimately used in the same time period.

The Director has concluded from this review of the current situation that control of all anorectic drugs is desirable at this time to insure that they will not become widely abused. This scheduling will fulfill the congressional mandate to act before substantial problems have arisen.

Based upon the investigations and review of the Bureau of Narcotics and Dangerous Drugs and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to sections 201 (a) and (b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811 (a), (b)), the Director of the Bureau of Narcotics and Dangerous Drugs finds that:

1. Based on information now available, phentermine has a potential for abuse less than the drugs or other substances currently listed in schedule II. Although chemically and pharmacologically this drug is closely related to the other anorectic drugs being proposed for control and to the stimulants now listed in schedule II, present data regarding excessive usage, diversion, illicit sales, and abuse of phentermine is not substantial enough to warrant a finding that it has potential for abuse equal to the stimulants in schedule II.

2. Phentermine has a currently accepted medical use in treatment in the United States.

3. Abuse of phentermine may lead to high psychological dependence.

Therefore, under the authority vested in the Attorney General by section 201 (a) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a), and delegated to the Director of the Bureau of Narcotics and Dangerous Drugs by § 0.100) of title 28 of the Code of Federal Regulations, the Director proposes that § 308.13 of title 21 of the Code of Federal Regulations be amended to read:

§ 308.13 Schedule III.

* * * * *

(b) *Stimulants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in schedule II which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under § 308.32, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances	1405
(2) Phentermine	1640

* * * * *

Conferences have been held between the Bureau and the Dorsey Laboratories, Division of Sandoz-Warner, Inc., one of the two manufacturers of phentermine in the United States. Dorsey has fully cooperated with the Bureau and has consented to the placement of phentermine in schedule III to insure that it does not become subject to abuse in the future.

All other interested persons are invited to submit their comments or objections in writing regarding this proposal. These comments or objections should state with particularity the issues concerning which the person desires to be heard. Comments and objections should be submitted in quintuplicate to the Hearing Clerk, Office of Chief Counsel, Bureau of Narcotics and Dangerous Drugs, Department of Justice, room 611, 1405 Eye Street NW., Washington, D.C. 20537, and must be received no later than June 7, 1973.

In the event that an interested party submits objections to this proposal which present reasonable grounds for this rule not to be finalized and requests a hearing in accordance with 21 CFR 308.45, the party will be notified by registered mail that a hearing on these objections will be held at 10 a.m. on June 11, 1973, in room 1210, 1405 Eye Street, NW., Washington, D.C. 20537. If objections submitted do not present such reasonable grounds, the party will be so advised by registered mail.

If no objections presenting reasonable grounds for a hearing on the proposal are received within the time limitations, and all interested parties waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Director may cancel the hearing and, after giving consideration to written comments, issue his final order pursuant to 21 CFR § 308.48 without a hearing.

Dated May 1, 1973.

JOHN E. INGERSOLL,
Director, Bureau of Narcotics and Dangerous Drugs.

[FR Doc.73-9070 Filed 5-8-73;8:45 am]

such free transportation is not used, the continued existence of Part 233 will work no more than harmless unpleasantness.

Since this rule imposes no burden upon any person but merely constitutes an amendment to the Board's regulations of an interpretive and technical nature, and as to relieve them consistent with the Postal Reorganization Act, the Board finds that notice and public procedure thereon are unnecessary and the amendment may become effective immediately.

In consideration of the foregoing, the Civil Aeronautics Board hereby amends and reissues Part 233 of its Economic Regulations (14 CFR Part 233), effective June 12, 1973, as follows:

Sec.
233.1 Postal employees to be carried free.
233.2 Issuance of credentials and authorization of travel by Postal Service.

AUTHORITY.—Sec. 204(a) and 403(j) of the Federal Aviation Act of 1958, as amended, 72 Stat. 743, 760; 49 U.S.C. 1324, 1373; sec. 2 of the Postal Reorganization Act, 84 Stat. 767; 39 U.S.C. 5007.

§ 233.1 Postal employees to be carried free.

Every air carrier transporting the mails shall carry, on any flight that it operates and without charge therefor, persons on duty in charge of the mails or traveling to or from such duty, upon the exhibition of their credentials.

§ 233.2 Issuance of credentials and authorization of travel by Postal Service.

With regard to free air travel by the persons described in § 233.1, the Postmaster General shall be responsible for: (a) The issuance of proper credentials for such persons and (b) the authorization of travel by such persons, subject to such rules and regulations as he may prescribe.

By the Civil Aeronautics Board.

[SEAL] EDWIN Z. HOLLAND,
Secretary.

[FR Doc.73-11978 Filed 6-14-73;8:45 am]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER C—DRUGS

PART 135a—NEW ANIMAL DRUGS FOR OPHTHALMIC AND TOPICAL USE

Chloramphenicol Ophthalmic Ointment, Veterinary

The Commissioner of Food and Drugs has evaluated a new animal drug application (65-150V) filed by EVSCO Pharmaceutical Corp., 3345 Royal Avenue, Oceanside, N.Y. 11572, proposing the safe and effective use of chloramphenicol ophthalmic ointment, veterinary, for the treatment of cats and dogs. The application is approved.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347; 21 U.S.C. 360b(i)) and under authority delegated to the Commissioner (21 CFR 2.120), part 135a is amended in § 135a by revising paragraphs (b) and (c) as follows:

§ 135a.29 Chloramphenicol ophthalmic ointment, veterinary.

* * * * *

(b) *Sponsor.*—See code No. 049 for use in accordance with paragraph (c)(1)(i) and code No. 053 for use in accordance with paragraph (c)(1)(ii) in § 135.501.

(c) *Conditions of use.*—(1) It is used in dogs and cats for the treatment of bacterial conjunctivitis caused by pathogens susceptible to chloramphenicol as follows:

(i) It is applied every 3 hours around the clock for 48 hours after which night installations may be omitted. Treatment should be continued for 2 days after the eye appears normal.

(ii) It is applied to affected eye four to six times daily for the first 72 hours depending upon the severity of the condition. A small amount of ointment should be placed in the lower conjunctival sac. Continue treatment for 48 hours after eye appears normal.

(2) Therapy for cats should not exceed 7 days. Prolonged use in cats may produce blood dyscrasias. If improvement is not noted in a few days a change of therapy should be considered. When infection is suspected as the cause of a disease process especially in purulent or catarrhal conjunctivitis, attempts should be made to determine through susceptibility testing, which antibiotics will be effective prior to applying ophthalmic preparations. This chloramphenicol product must not be used in animals producing meat, eggs, or milk. The length of time that residues persist in milk or tissues has not been determined.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date.—This order shall be effective on June 15, 1973.

(Sec. 512(i), 82 Stat. 347; 21 U.S.C. 360b(i).)

Dated June 8, 1973.

C. D. VAN HOUWELING,
Director,
Bureau of Veterinary Medicine.

[FR Doc.73-11927 Filed 6-14-73;8:45 am]

CHAPTER II—BUREAU OF NARCOTICS AND DANGEROUS DRUGS, DEPARTMENT OF JUSTICE

PART 308—SCHEDULES OF CONTROLLED SUBSTANCES

Placement of Benzphetamine, Chlorphentermine, Clortermine, Diethylpropion, Mazindol, Phendimetrazine, and Phentermine in Schedule III, and Placement of Fenfluramine in Schedule IV

Notices were published in the FEDERAL REGISTER on May 9 and 10, 1973, proposing placement of benzphetamine (38 FR 19119), chlorphentermine (33 FR 12120), clortermine (38 FR 12121), diethylpropion (38 FR 12230), mazindol (38 FR 12124), phendimetrazine (38 FR 12126), and phentermine (38 FR 12127) in schedule III of the Controlled Substances Act, and fenfluramine (38 FR 12123) in schedule IV of the Controlled Substances Act. All interested persons were given until June 7, 1973, to file objections, comments, or requests for a hearing. A notice was published in the FEDERAL REGISTER on May 31, 1973, extending the time for filing to June 11, 1973 (38 FR 14238).

No objections nor requests presenting reasonable grounds for a hearing regarding the proposed orders on benzphetamine, chlorphentermine, clortermine, mazindol, and phendimetrazine were received. An objection and request for a hearing regarding the proposed orders on phentermine and fenfluramine was filed on May 21, 1973, and supplemented on June 11, 1973, by Pennwalt Corp. Details of these filings are discussed under the headings "Fenfluramine" and "Phentermine" below. An objection and request for a hearing regarding the proposed order on diethylpropion was filed on June 11, 1973, by Merrell National Laboratories, a division of Richardson Merrell, Inc. Details on this filing are discussed under the heading "Diethylpropion" below.

A comment was filed on May 23, 1973, by Lexington Chemical Co., Inc., Waltham, Mass., requesting that adequate time be provided between the publication of a final order and the effective date of such an order to provide industry sufficient opportunity to adjust to the new controls. The Bureau has considered this suggestion and believes that the effective dates set in this order comply with the spirit of the comment.

BENZPHETAMINE

Based upon the investigations and review of the Bureau of Narcotics and Dangerous Drugs and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to section 201 (a) and (b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811 (a), (b)), the Director of the Bureau of Narcotics and Dangerous Drugs finds that:

1. Based on information now available, benzphetamine has a potential for abuse less than the drugs or other substances currently listed in schedule II. Although chemically and pharmacologically this drug is closely related to the other anorectic drugs now being controlled and to the stimulants now listed in schedule II, present data regarding excessive usage, diversion, illicit sales, and abuse of benzphetamine is not substantial enough to warrant a finding that it has a potential for abuse equal to the stimulants in schedule II.

2. Benzphetamine has a currently accepted medical use in treatment in the United States.

3. Abuse of benzphetamine may lead to high psychological dependence.

The Director has concluded from his review of the current situation that control of all anorectic drugs, including benzphetamine, is desirable at this time to insure that they will not become widely abused. This scheduling will fulfill the

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[illegible] 61[illegible] 6[illegible] [text omitted.]

[illegible] phenmetrazine [illegible] the United States, has fully cooperated with the Bureau and has consented to the placement of benzphetamine in schedule III to insure that it does not become subject to abuse in the future.

CHLORPHENTERMINE

Based upon the investigations and review of the Bureau of Narcotics and Dangerous Drugs and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to sections 201 (a) and (b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811 (a), (b)), the Director of the Bureau of Narcotics and Dangerous Drugs finds that:

1. Based on information now available, chlorphentermine has a potential for abuse less than the drugs or other substances currently listed in schedule II. Although chemically and pharmacologically this drug is closely related to the other anorectic drugs now being controlled and to the stimulants now listed in schedule II, present data regarding excessive usage, diversion, illicit sales, and abuse of chlorphentermine is not substantial enough to warrant a finding that it has a potential for abuse equal to the stimulants in schedule II.

2. Chlorphentermine has a currently accepted medical use in treatment in the United States.

3. Abuse of chlorphentermine may lead to high psychological dependence.

The Director has concluded from his review of the current situation that control of all anorectic drugs, including chlorphentermine, is desirable at this time to insure that they will not become widely abused. This scheduling will fulfill the congressional mandate to act before substantial problems have arisen.

CLORTERMINE

Based upon the investigations and review of the Bureau of Narcotics and Dangerous Drugs and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to sections 201(a) and (b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a), (b)), the Director of the Bureau of Narcotics and Dangerous Drugs finds that:

1. Based on information now available, clortermine has a potential for abuse less than the drugs or other substances currently listed in schedule II. Although chemically and pharmacologically this drug is closely related to the other anorectic drugs now being controlled and to the stimulants now listed in schedule II present data regarding these properties is not substantial enough to warrant a finding that it has a potential for abuse equal to the stimulants in schedule II.

2. Clortermine will, upon the approval of new drug application by the FDA, have a currently accepted medical use in treatment in the United States.

[illegible] concluded from his review of the current situation that control of all anorectic drugs, including clortermine, is desirable at this time to insure that they will not become widely abused. This scheduling will fulfill the congressional mandate to act before substantial problems have arisen. The USV Pharmaceutical Corp., the only firm intending to market clortermine in the United States, has fully cooperated with the Bureau. Upon the conditions set forth in a letter to the Bureau from counsel for USV Pharmaceutical Corp. dated April 20, 1973, the manufacturer has consented to the placement of clortermine in schedule III to insure that it does not become subject to abuse in the future.

DIETHYLPROPION

The Bureau proposed placement of diethylpropion in schedule III, because it is one of the anorectics, control of which is desirable at this time (38 FR 12127).

Merrell National Laboratories, a division of Richardson Merrell, Inc., the only manufacturer of diethylpropion in the United States, filed comments, objections, and a request for a hearing regarding diethylpropion on June 11, 1973. In light of these objections and request for a hearing, the Director will not issue a final order controlling diethylpropion at this time.

FENFLURAMINE

The Pennwalt Corp., a manufacturer of a phentermine product called "Ionamin", filed comments, objections, and a request for a hearing regarding phentermine and fenfluramine on May 21, 1973. The comments of Pennwalt Corp. include the following paragraphs:

Pennwalt Corp. has no objection to the scheduling of "Ionamin" in schedule III, provided that the same scientific and legal principles which would lead to this scheduling of "Ionamin" are also applied to any other relevant product. Our objection, specifically, is that on the basis of information available to Pennwalt Corp. and to the field generally, there would appear to be more basis, or at least an equal basis, for placing fenfluramine in an equal or more restrictive schedule than "Ionamin".

It is Pennwalt's position that the Department of Health, Education, and Welfare erred in recommending to the BNDD that the products listed above, except for fenfluramine, be placed in schedule III, and that fenfluramine be placed in schedule IV. The basis for Pennwalt's position is twofold:

1. To the best of Pennwalt's knowledge, information and belief, the record of "Ionamin" with respect to abuse or any adverse consequences hardly rises to the de minimis level. There is no study, to our knowledge, by any reputable physician or institution which suggests that the risks, if any, in marketing "Ionamin" rise to the level of risk apparently already established for the use of fenfluramine.

2. The evidence with respect to the use of fenfluramine in Scotland, South Africa, and Jamaica, suggests to the physicians reporting their studies the risk of serious abuse, and serious withdrawal symptoms following the use of fenfluramine in controlled studies.

[illegible] Pennwalt is aware that the Bureau of Narcotics and Dangerous Drugs, and presumably the Department of Health, Education, & Welfare, were aware of [illegible] South Africa, as stated at page 12123 of the FEDERAL REGISTER, volume 38, No. 89, but Pennwalt believes that the material [illegible] herewith demonstrates the basis upon which evaluation of fenfluramine should be made, when compared to the other products noted above.

In summary, fenfluramine appears to be the only product as to which there is serious adverse medical literature of record, and Pennwalt therefore believes that, as noted above, the scheduling of fenfluramine should be at no more permissive schedule than provided for the other relevant products.

On June 1, 1973, the Bureau notified Pennwalt Corp. that no objection has been raised regarding the control of fenfluramine, but only to the propriety of its placement in schedule IV. The Bureau interpreted this objection as a proposal to control fenfluramine in schedule III or, if fenfluramine is controlled in schedule IV as proposed, a petition to transfer fenfluramine from schedule IV to schedule III. Pennwalt Corp. was informed that, unless the company requested otherwise, the Bureau would consider the comments as a petition to place fenfluramine in schedule III and not as an objection to the current proposal to place fenfluramine in schedule IV. (A hearing on the proper schedule for fenfluramine would therefore be held only after receipt of the report of the Secretary of Health, Education, and Welfare, which has been now requested.) Pennwalt Corp. has not requested otherwise and no other objections have been received regarding the fenfluramine proposal.

Based upon the investigations and review of the Bureau of Narcotics and Dangerous Drugs and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to sections 201 (a) and (b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811 (a), (b)), the Director of the Bureau of Narcotics and Dangerous Drugs finds that:

1. Based on information evaluated up to this time, fenfluramine has a low potential for abuse relative to the drugs or other substances currently listed in schedule III. Although chemically and/or pharmacologically this drug is related to the other anorectic drugs now being controlled and to the stimulants now listed in schedule II, present data regarding excessive usage, diversion, illicit sales, and abuse in other countries is not substantial enough to warrant a finding that fenfluramine has a potential for abuse equal to the stimulants in schedule II or to the other anorectic drugs now being controlled. In addition, certain tests cited in the letter from the Department of Health, Education, and Welfare suggest a lower abuse potential for fenfluramine.

2. Fenfluramine will, upon the approval of a new drug application by the FDA, have a currently accepted medical use in treatment in the United States.

3. Abuse of fenfluramine may lead to limited physical dependence relative to the amphetamines or other substances in schedule III.

In making these findings, the Director is aware that material filed by the Pennwalt Corp., material previously referred to the Department of Health, Education, and Welfare for evaluation concerning possible abuse of fenfluramine in South Africa (see 38 FR 12125, May 9, 1973), and other evidence which may become available might necessitate findings regarding the abuse potential and dependence liability of fenfluramine justifying placement of the substance in schedule III. Therefore, the findings made in this order should not be construed as precluding new findings regarding fenfluramine in the near future in light of such evidence.

The Director has concluded from his review of the current situation that control of all anorectic drugs, including fenfluramine, is at this time to prevent their becoming widely abused. This scheduling will fulfill the congressional mandate to act before substantial problems have arisen. The A. H. Robins Co., the only firm intending to market fenfluramine in the United States, has fully cooperated with the Bureau and has consented to the placement of fenfluramine in schedule IV to insure that it does not become subject to abuse in the future.

MAZINDOL

Based upon the investigations and review of the Bureau of Narcotics and Dangerous Drugs and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to sections 201 (a) and (b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811 (a) and (b)), the Director of the Bureau of Narcotics and Dangerous Drugs finds that:

1. Based on information now available, mazindol has a potential for abuse less than the drugs or other substances currently listed in schedule II. Although pharmacologically this drug is closely related to the other anorectic drugs now being controlled and to the stimulants now listed in schedule II, present data regarding these properties is not substantial enough to warrant a finding that it has a potential for abuse equal to the stimulants in schedule II.

2. Mazindol will, upon the approval of a new drug application by the Food and Drug Administration, have a currently accepted medical use in treatment in the United States.

3. Abuse of mazindol may lead to high psychological dependence.

The Director has concluded from his review of the current situation that control of all anorectic drugs, including mazindol, is desirable at this time to insure that they will not become widely abused. This scheduling will fulfill the congressional mandate to act before substantial problems have arisen. Sandoz-Wander, Inc., the only firm intending to market mazindol. The United States, has fully cooperated with the Bureau and has consented to the placement of mazindol in schedule III to insure that it does not become subject to abuse in the future.

PHENDIMETRAZINE

Based upon the investigations and review of the Bureau of Narcotics and Dangerous Drugs and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to sections 201(a) and (b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811 (a), (b)), the Director of the Bureau of Narcotics and Dangerous Drugs finds that:

1. Based on information now available, phendimetrazine has a potential for abuse less than the drugs or other substances currently listed in schedule II. Although chemically and pharmacologically this drug is closely related to the other anorectic drugs now being controlled and to the stimulants now listed in schedule II, present data regarding excessive usage, diversion, illicit sales, and abuse of phendimetrazine is not substantial enough to warrant a finding that it has a potential for abuse equal to the stimulants in schedule II.

2. Phendimetrazine has a currently accepted medical use in treatment in the United States.

3. Abuse of phendimetrazine may lead to high psychological dependence.

The Director has concluded from his review of the current situation that control of all anorectic drugs, including phendimetrazine, is desirable at this time to insure that they will not become widely abused. This scheduling will fulfill the congressional mandate to act before substantial problems have arisen. The Ayerst Laboratories Division of the American Home Products Corp., the largest manufacturer of phendimetrazine in the United States and the only firm with a new drug application for phendimetrazine approved by the Food and Drug Administration, has fully cooperated with the Bureau and has consented to the placement of phendimetrazine in schedule III to insure that it does not become subject to abuse in the future.

PHENTERMINE

The Bureau proposed placement of phentermine in schedule III, because it is one of the anorectics control of which is desirable at this time (38 FR 12127).

The Dorsey Laboratories, Division of Sandoz-Warner, Inc., one of the two manufacturers of phentermine in the United States, has fully cooperated with the Bureau and has consented to the placement of phentermine in schedule III to insure that it does not become subject to abuse in the future.

Pennwalt Corp., the other manufacturer of phentermine in the United States, filed comments, objections, and a request for a hearing regarding phentermine and fenfluramine on May 21, 1973. The major portion of these comments were set forth above under the heading "Fenfluramine." On June 1, 1973, Pennwalt Corp. supplemented its filing regarding its objections on phentermine. In lieu of these objections and request for a hearing, the Director will not issue a final order controlling phentermine at this time.

CONCLUSION

Therefore, under the authority vested in the Attorney General by section 201(a) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a)), and delegated to the Director of the Bureau of Narcotics and Dangerous Drugs by § 0.100 of title 28 of the Code of Federal Regulations, the Director orders that:

1. Paragraph (b) of § 308.13 of title 21 of the Code of Federal Regulations be amended to read:

§ 308.13 Schedule III.

* * * * *

(b) *Stimulants.*—Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in schedule II which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under § 308.32, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances 1405
(2) Benzphetamine 1228
(3) Chlorphentermine 1645
(4) Clortermine 1647
(5) Mazindol 1605
(6) Phendimetrazine 1615

* * * * *

2. Section 308.14 of title 21 of the Code of Federal Regulations be amended by the addition of a new paragraph to read:

§ 308.14 Schedule IV.

* * * * *

(c) *Fenfluramine.*—Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible:

(1) Fenfluramine 1670

FUTURE ACTION REGARDING ANORECTICS

Because of the similarities among the substances controlled by this order, and between those substances and the stimulants currently listed in schedule II, the Director is controlling these substances at this time in order to prevent their becoming the subject of abuse as amphetamines become less available in the illicit

market through the operation of the Bureau's regulatory controls and criminal enforcement actions. The Director believes that evidence indicates these anorectics may be future targets of stimulant abusers.

The Bureau will monitor the manufacture, distribution, and use of benzphetamine, chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine in the United States, paying special attention to indicators of diversion (such as shortages in accountability audits of distributors and dispensers, thefts from handlers, and availability on the illicit market) and to other indications which indicate that any of these substances are actually being abused (such as excessive prescribing and dispensing, reports of adverse reactions and overdoses, and other medical experiences).

The Bureau will also consider all available, clinical and other research in abusability, dependence-creating, and dependence-sustaining characteristics of any of these substances. If, after 18 months during which these drugs are marketed, experience suggests that any of them have not been subject to significant diversion or abuse, the Director will review the necessity and desirability of maintaining it in schedule III (or, in case of fenfluramine, schedule IV) and will request from the Secretary of Health, Education, and Welfare a new scientific and medical evaluation, and his recommendation, as to whether that substance should be so controlled or removed as a controlled substance.

Any interested person may petition the Bureau to decontrol any of these substances at any time. If any petition is received to decontrol any one of these substances, or if the Director, based upon the review mentioned above, requests the evaluation and recommendation of the Secretary of Health, Education, and Welfare on any of these substances, all of the remaining substances will also be reviewed and, where appropriate, evaluations and recommendations regarding them will also be requested of the Secretary.

EFFECTIVE DATES

The requirements imposed upon the anorectic substances controlled by this order shall become effective as follows:

1. *Registration.*—Unless currently registered to conduct that activity with schedule III (or, in the case of fenfluramine, schedule IV) nonnarcotic substances, or unless exempted from registration by law, or pursuant to §§ 301.24–301.28 or 311.24–311.28 of title 21 of the Code of Federal Regulations, any person who manufactures, distributes, dispenses, imports, or exports benzphetamine, chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine, or who proposes to engage in the manufacture, distribution, dispensing, importation, or exportation of any of those substances, shall obtain a registration to conduct that activity on or before August 1, 1973.

2. *Security.*—Benzphetamine, chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine must be manufactured, distributed, and stored in accordance with §§ 301.71, 301.72(b), 301.73, 301.74, 301.75(b), and 301.76 of title 21 of the Code of Federal Regulations on or before September 1, 1973. In the event that this poses special hardships, the Bureau will entertain any justified requests for extensions of time.

3. *Labeling and packaging.*—All labels on commercial containers of, and all labeling of, clortermine, fenfluramine, and mazindol which are packaged after June 15, 1973, shall comply with the requirements of §§ 302.03–302.05 and 302.08 of title 21 of the Code of Federal Regulations. In accordance with § 302.06 (c) of title 21 of the Code of Federal Regulations, the Director finds that early compliance with these requirements is necessitated by the fact that if these drugs, which have never before been marketed in the United States, fail to bear the appropriate symbol, physicians, pharmacists, distributors, and other handlers may not be aware that these drugs are now controlled under the Controlled Substances Act, thereby endangering the public health and safety. As noted above, early control of these substances has been undertaken to prevent abuse before it begins; prompt and adequate notice of control is essential to carry out this purpose.

All labels on commercial containers of, and all labeling of benzphetamine, chlorphentermine, and phendimetrazine which are packaged after September 1, 1973, shall comply with the requirements of §§ 302.03–302.05 and 302.08 of title 21 of the Code of Federal Regulations. In accordance with § 302.06(c) of title 21 of the Code of Federal Regulations, the Director finds that early compliance with these requirements is necessitated, again, by the fact that early control of these substances has been undertaken to prevent abuse before it becomes widespread; prompt and adequate notice of control is essential to carry out this purpose and thereby protect the public health and safety. In addition, the Director believes it would be unfair and discriminatory to allow any greater period of time between the effective dates of labeling for the new anorectics and the effective dates for those anorectics already being marketed.

In the event these effective dates pose special hardships on any manufacturer, the Bureau will entertain any justified requests for an extension of time.

4. *Inventory.*—Every registrant required to keep records who possesses any quantity of benzphetamine, chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine shall take an inventory of all stocks of those substances on hand on September 1, 1973.

5. *Record.*—All registrants required to keep records pursuant to part 304 of title 21 of the Code of Federal Regulations shall maintain such records on benzphetamine, chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine commencing on the date on which the inventory of those substances is taken.

6. *Prescriptions.*—All prescriptions for products containing benzphetamine, chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine shall comply with §§ 306.01–306.05 and 306.21–306.25 of title 21 of the Code of Federal Regulations no later than September 1, 1973. Any prescription for any of the foregoing products which was issued before March 1, 1973, or which has been refilled more than five times, may not be refilled after September 1, 1973.

7. *Importation and exportation.*—All importation and exportation of benzphetamine, chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine on and after September 1, 1973, shall be in compliance with part 312 of title 21 of the Code of Federal Regulations.

8. *Criminal liability.*—Any activity with benzphetamine, chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine, not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act, conducted after June 15, 1973, shall be unlawful, except that any person who is not now registered to handle these substances but who is entitled to registration under these acts may continue to conduct normal business or professional practice with these substances between the date on which this order is published and the date on which he obtains the proper registration.

9. *Other.*—In all other respects, this order is effective on June 15, 1973.

Dated June 12, 1973.

JOHN E. INGERSOLL,
Director, Bureau of Narcotics and Dangerous Drugs.

[FR Doc.73-11935 Filed 6-14-73;8:45 am]

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER C—AIR PROGRAMS

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Approval of Plan Revisions

On October 28, 1972 (37 FR 23085), pursuant to section 110(c) of the Clean Air Act, the Administrator promulgated regulations for several State implementation plans to correct disapproved portions of plans submitted by the States. A regulation providing for the review of new sources and modifications was promulgated for the State of New Jersey (37 FR 23091). Section 110(a)(2) of the Clean Air Act and 40 CFR 51.18 require that State implementation plans contain legally enforceable procedures which shall enable the States to prevent construction of new sources and modification of existing sources if such construction or modification will result in a violation of applicable portions of the State's control strategy or will interfere with attainment or maintenance of a national ambient air quality standard. The State of New Jersey, on March 22, 1973, submitted amended chapters 9 (permits) and 13 (ambient quality standards) of the New Jersey Air Pollution

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Title 21—Food and Drugs

CHAPTER II—BUREAU OF NARCOTICS AND DANGEROUS DRUGS, DEPARTMENT OF JUSTICE

PART 308—SCHEDULES OF CONTROLLED SUBSTANCES

Diethylpropion and Phentermine; Temporary Placement in Schedule IV; Interim Regulations

Notices were published in the FEDERAL REGISTER on May 9 and 10, 1973, proposing placement of benzphetamine (38 FR 19119), chlorphentermine (38 FR 12120), clortermine (38 FR 12121), diethylpropion (38 FR 12230), mazindol (38 FR 12124), phendimetrazine (38 FR 12126), and phentermine (38 FR 12127) in Schedule III of the Controlled Substances Act, and fenfluramine (38 FR 12123) in Schedule IV of the Controlled Substances Act. All interested persons were given until June 7, 1973, to file objections, comments or requests for a hearing. A notice was published in the FEDERAL REGISTER on May 31, 1973, extending the time for filing to June 11, 1973, (38 FR 14288).

On June 15, 1973, a final order was issued placing benzphetamine, chlorphentermine, clortermine, mazindol, and phendimetrazine in Schedule III of the Controlled Substances Act and fenfluramine in Schedule IV of the Controlled Substances Act (38 FR 15719).

Objections and a request for a hearing were filed on the proposal to control diethylpropion by Merrell National Laboratories, a division of Richardson Merrell, Inc., the manufacturer of that substance. Objections and a request for a hearing were filed on the proposal to control phentermine by Pennwalt Corporation, a manufacturer of that substance. The Bureau is currently seeking acceptable dates for hearings on these objections.

Until such hearings can be completed, however, the Bureau believes that interim control of diethylpropion and phentermine is desirable. These two substances are reported to be among the most widely prescribed of the non-amphetamine anorectic drugs in the United States. The Bureau's concern that such drugs are likely targets for future abuse applies with special force to diethylpropion and phentermine because of this wide availability. In addition, in controlling benzphetamine, clortermine, mazindol and phendimetrazine, the Bureau had indicated to manufacturers that their consenting to control would not be allowed to place them at a competitive disadvantage with other substances being proposed for Schedule III. In light of these considerations, the Director requested that Merrell National Laboratories and Pennwalt Corporation consent, respectively, to the placement of diethylpropion and phentermine in Schedule IV of the Controlled Substances Act in the interim before hearings can be held and a final order issued on the proposals to place each substance in Schedule III.

Merrell National Laboratories and Pennwalt Corporation have cooperated with the Director in this request in order to assure that any possibility of abuse of diethylpropion and phentermine during the next weeks is minimized. Both manufacturers have stated, and the Bureau has agreed, that this consent does not constitute an admission to any facts or findings regarding the abuse potential or dependence liability of the two substances, nor a waiver of the right to contest any assertion of fact or law involved in the hearings on placement in Schedule III, nor a withdrawal of the requests for such hearings, nor does it alter the burden of proof on any issue of fact in such hearings. In the same manner this interim action in no way affects the Bureau's proposal that diethylpropion and phentermine be placed in Schedule III. For all parties this interim order represents the most expedient course of action necessary to protect public health and safety, to preserve the rights of the manufacturers of diethylpropion and phentermine, and to observe the legitimate interests of the manufacturers of the other anorectic drugs now controlled.

The Bureau construes that the published proposals to place diethylpropion and phentermine in Schedule III comply with the procedures required by section 201 of the Controlled Substances Act for the placement of these substances in Schedule IV, in this situation. The pertinent regulatory controls on Schedules III and IV are substantially identical. There being no objections to the placement of these substances in Schedule III (other than those of the two manufacturers), it would appear unlikely that anyone would now object to their placement in Schedule IV, except possibly for manufacturers of other anorectic drugs in competition with diethylpropion and phentermine. The Bureau has consulted with these manufacturers and each agreed to this interim action. The USV Pharmaceutical Corporation so agreed on conditions which are acceptable to the Bureau and which will be set forth in a letter to be dated July 2, 1973 from counsel for the Corporation. Therefore, under these unusual circumstances the Director finds that section 201 has been complied with and no further proposal be made but an order issued to place diethylpropion and phentermine in Schedule IV at this time.

DIETHYLPROPION

Based upon the investigations and review of the Bureau of Narcotics and Dangerous Drugs and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education and Welfare, received pursuant to sections 201(a) and (b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a), (b)), the Director of the Bureau of Narcotics and Dangerous Drugs finds that:

1. Based on information now available, diethylpropion has a low potential for abuse relative to the drugs or other substances currently listed in Schedule III.

2. Diethylpropion has a currently accepted medical use in treatment in the United States.

3. Abuse of diethylpropion may lead to limited psychological dependence relative to the drugs or other substances in Schedule III.

The Director has concluded from his review of the current situation that control of all anorectic drugs, including diethylpropion, is desirable at this time to insure that they will not become widely abused. While instances of abuse with diethylpropion are irregular and infrequent, the Director believes that scheduling will prevent diethylpropion from becoming the subject of abuse as amphetamines become increasingly unavailable in the illicit market. In this regard the Bureau recognizes that the manufacturer has presented data indicating that in environments where amphetamines have been banned, diethylpropion has not become the subject of increased abuse. This scheduling will fulfill the congressional mandate to act before substantial problems have arisen. Merrell National Laboratories, a division of Richardson Merrell, Inc., the only manufacturer of diethylpropion in the United States, has participated in conferences with the Bureau and cooperated fully by making available to both the Bureau and the Department of Health, Education and Welfare an extensive analysis of published and unpublished reports of diethylpropion abuse. Upon the conditions set forth in a letter to the Bureau from counsel for Merrell National Laboratories, dated June 29, 1973, to which the Bureau agrees, the manufacturer has consented to the placement of diethylpropion in Schedule IV to insure that it does not become subject to abuse in the period prior to final action on the proposal to place diethylpropion in Schedule III.

PHENTERMINE

Based upon the investigations and review of the Bureau of Narcotics and Dangerous Drugs and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to sections 201(a) and (b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a), (b)), the Director of the Bureau of Narcotics and Dangerous Drugs finds that:

1. Based on information now available, phentermine has a low potential for abuse relative to the drugs or other substances currently listed in Schedule III.

2. Phentermine has a currently accepted medical use in treatment in the United States.

3. Abuse of phentermine may lead to limited psychological dependence relative to the drugs or other substances in Schedule III.

The Director has concluded from his review of the current situation that control of all anorectic drugs, including phentermine, is desirable at this time to insure that they will not become widely abused. This scheduling will fulfill the congressional mandate to act before substantial problems have arisen. The Dorsey Laboratories, Division of Sandoz-Wander, Inc., one of the two manufacturers of phentermine in the United States, has fully cooperated with the Bureau and has consented to the placement of phentermine in Schedule III to insure that it does not become subject to abuse in the future. The Pennwalt Corporation, the other manufacturer of phentermine in the United States, has participated in conferences with the Bureau. Upon the conditions set forth in a letter to the Bureau from counsel for Pennwalt Corporation, dated June 26, 1973, to which the Bureau agrees, the manufacturer has consented to the placement of phentermine in Schedule IV to insure that it does not become subject to abuse in the period prior to final action on the proposal to place phentermine in Schedule III.

CONCLUSION

Therefore, under the authority vested in the Attorney General by section 201 (a) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a)), and delegated to the Director of the Bureau of Narcotics and Dangerous Drugs by § 0.100 of Title 28 of the Code of Federal Regulations, the Director orders that § 308.14 of Title 21 of the Code of Federal Regulations be amended by the addition of a new paragraph to read:

§ 308.14 Schedule IV.

* * * * *

(d) *Stimulants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Diethylpropion	1610
(2) Phentermine	1640

FUTURE ACTION REGARDING ANORECTICS

Because of the similarities among the substances controlled by this order, and between those substances and the stimulants currently listed in Schedules II and III, the Director is controlling these substances at this time in order to prevent their becoming the subject of abuse as amphetamines become less available in the illicit market through the operation of the Bureau's regulatory controls and criminal enforcement actions. The Director believes that evidence suggests these anorectics may be future targets of stimulant abusers.

The Bureau intends to proceed to hearings on the placement of diethylpropion and phentermine in Schedule III in the near future. The times and places of such hearings will be announced shortly.

The Bureau, over a longer period, will monitor the manufacture, distribution, and use in the United States of diethylpropion and phentermine, as well as those anorectic drugs controlled on June 15, 1973, paying special attention to indicators of diversion (such as shortages in accountability audits of distributors and dispensers, thefts from handlers, and availability on the illicit market) and to other indicators which indicate that any of these substances are actually being abused (such as excessive prescribing and dispensing, reports of adverse reactions and overdoses, and other medical experiences). The Bureau will also consider, if available, clinical and other research in abusability, dependence-creating, and dependence-sustaining characteristics of any of these substances. If, after 18 months during which these drugs are marketed, experience suggests that any of them have not been subject to significant diversion or abuse, the Director will review the necessity and desirability of maintaining it under control and will request from the Secretary of Health, Education, and Welfare a new scientific and medical evaluation, and his recommendation, as to whether that substance should be so controlled or removed as a controlled substance.

Any interested person may petition the Bureau to decontrol any of these substances at any time. If any petition is received to decontrol any one of these substances, or if the Director, based upon the review mentioned above, requests the evaluation and recommendation of the Secretary of Health, Education and Welfare on any of these substances, all of the remaining substances will also be reviewed and, where appropriate, evaluations and recommendations regarding them will also be requested of the Secretary.

Effective dates. The requirements imposed upon the anorectic substances controlled by this order shall become effective as follows:

1. *Registration.* Unless currently registered to conduct that activity with Schedule IV nonnarcotic substances, or unless exempted from registration by law or pursuant to §§ 301.24–301.28 or 311.24–311.28 of Title 21 of the Code of Federal Regulations, any person who manufactures, distributes, dispenses, imports or exports diethylpropion or phentermine or who proposes to engage in the manufacture, distribution, dispensing, importation, or exportation of either of those substances, shall obtain a registration to conduct that activity on or before August 1, 1973.

2. *Security.* Diethylpropion and phentermine must be manufactured, distributed and stored in accordance with §§ 301.71, 301.72(b), 301.73, 301.74, 301.75(b) and 301.76 of Title 21 of the Code of Federal Regulations on or before September 1, 1973. In the event that this poses special hardships, the Bureau will entertain any justified requests for extensions of time.

3. *Labeling and packaging.* All labels on commercial containers of, and all labeling of, diethylpropion and phentermine which are packaged after September 1, 1973, shall comply with the requirements of §§ 302.03–302.05 and 302.08 of Title 21 of the Code of Federal Regulations. In accordance with § 302.06(c) of Title 21 of the Code of Federal Regulations, the Director finds that early compliance with these requirements is necessitated by the fact that early control of these substances has been undertaken to prevent abuse before it becomes widespread; prompt and adequate notice of control is essential to carry out this purpose and thereby protect the public health and safety. In addition, the Director believes it would be unfair and discriminatory to allow any greater period of time between the effective dates of labeling for the anorectics newly approved for marketing and the effective dates for those anorectics which have been marketed for some period of time. In the event these effective dates pose special hardships on any manufacturer, the Bureau will entertain any justified requests for an extension of time.

4. *Inventory.* Every registrant required to keep records who possesses any quantity of diethylpropion or phentermine

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shall take an inventory of all stocks of those substances on hand on September 1, 1973.

5. *Records.* All registrants required to keep records pursuant to Part 304 of Title 21 of the Code of Federal Regulations shall maintain such records on diethylpropion and phentermine commencing on the date on which the inventory of those substances is taken.

6. *Prescriptions.* All prescriptions for products containing diethylpropion and phentermine shall comply with §§ 306.01–302.06 and 306.21–206.25 of Title 21 of the Code of Federal Regulations no later than September 1, 1973. Any prescription for any of the foregoing products which was issued before March 1, 1973, or which has been refilled more than five times, may not be refilled after September 1, 1973.

7. *Importation and exportation.* All importation and exportation of diethylpropion and phentermine on and after September 1, 1973, shall be in compliance with Part 312 of Title 21 of the Code of Federal Regulations.

8. *Criminal liability.* Any activity with diethylpropion or phentermine, not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act, conducted after the date this order is published in the FEDERAL REGISTER shall be unlawful, except that any person who is not now registered to handle these substances but who is entitled to registration under those Acts may continue to conduct normal business or professional practice with those substances between the date on which this order is published and the date on which he obtains the proper registration.

9. *Other.* In all other respects, this order is effective on July 6, 1973.

Dated: June 29, 1973.

JOHN E. INGERSOLL,
Director, Bureau of Narcotics and Dangerous Drugs.

[FR Doc.73-13691 Filed 7-5-73;8:45 am]

federal register

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[Docket No. 73-16]

PROPOSED PLACEMENT OF PHENTERMINE IN SCHEDULE III

Notice of Hearing

On May 9, 1973, the Bureau of Narcotics and Dangerous Drugs (presently the Drug Enforcement Administration), Department of Justice, proposed that phentermine be placed into Schedule III of the Controlled Substances Act (38 FR 12127).

All interested persons were given until June 7, 1973, to file objections, comments or requests for a hearing. A notice was published in the FEDERAL REGISTER on May 31, 1973, extending the time for filing to June 11, 1973 (38 FR 14288).

A manufacturer of phentermine, Pennwalt Corporation, filed comments, objections, and a request for a hearing on May 21, 1973, regarding the placement of phentermine and fenfluramine into schedules of control under the Controlled Substances Act. On June 11, 1973, Pennwalt Corporation supplemented its filing regarding its objections on phentermine.

On July 6, 1973, a notice was published in the FEDERAL REGISTER (38 FR 18013) placing phentermine in Schedule IV pending the hearing on the proposal to place it in Schedule III. It was also stated that the time and place for the hearing would be announced shortly.

Notice is hereby given that a hearing in the matter of placing phentermine in Schedule III will commence on October 31, 1973, at 10 a.m. in Room 1211 of the Drug Enforcement Administration, 1405 I Street, NW., Washington, D.C. 20537.

Any interested person desiring to participate in this hearing, but not yet made a party, shall file a notice of his intention to participate in the form prescribed in § 1316.48 of Title 21 of the Code of Federal Regulations on or before October 31, 1973, with the Hearing Clerk, Drug Enforcement Administration, 1405 I Street, NW., Washington, D.C. 20537.

Dated: October 9, 1973.

JOHN R. BARTELS, Jr.,
Acting Administrator,
Drug Enforcement Administration.

[FR Doc.73-21904 Filed 10-12-73;8:45 am]

Phendimetrazine

A. The following sources of information have been searched.

1. NCDAI computer using generic and trade names.

2. Medline

3. Chemical Abstracts using the chemical name
Vol. 41 - 1947 to Vol. 75 - 1971.

4. Index Medicus by generic name

5. Toxicology Bibliography Vol. 1 (1968) to Volume 5 #2 - (1972)

6. Exerpta Medica

a. Pharmacology and Toxicology (1966-1971)

b. Psychiatry (1968-1971)

c. Public Health (1968-1971)

7. SCIL reports for FY 71, FY 72 and first quarter of FY 73 - as phendimetrazine tartrate #1620

8. Poison Control Data

B. The following information was found:

1. Phendimetrazine is marketed as Plegine by Ayerst as 35 mg tablets and as Statobex by Lemmon as 35 mg tablets

2. There is an active NDA- 12-248 but this NDA was not reviewed since a synopsis was prepared by FDA and is attached.

3. The drug was marketed as Dietrol by American Hygienic Co. but has been discontinued.

4. Poison Control Data - only one case

Code #	Drug	Age	Sex	Date	Location	Category
245848	Plegine	16	F	4/72	Maryland	2(kicks)

5. SCIL - 3 exhibits

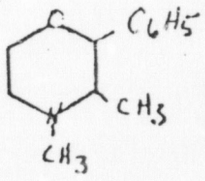
Lab #	BNDD#	Quantity	Suspected Firm	Potency	Location	Date
9013	J1710029	75 tabs.	Ayerst	35 mg/ tab.	Louisiana	5/27/71
6260	-	4 tabs	Ayerst	-	Illinois	2/18/72
A0339	-	33 tabs.	Ayerst	-	Wash. DC	1/21/72

6. Literature search revealed no report of abuse. The drug name was not listed for the NCDAI Computer, Index Medicus and Toxicology Bibliography

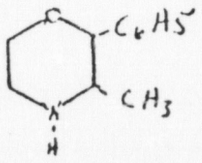
7. Searching Medline-found only 6 titles

C. Discussion

1. Phendimetrazine is similar in structure to phenmetrazine



Phendimetrazine



Phenmetrazine

2. It is prepared from 2-phenyl-2-hydroxy-3,4 dimethylmorpholine British patent 791,416 (1958) and 862,198 (1961)

3. Cox and Maichel compared the anorexigenic and behavioral potency of phenylethylamines in rats and found the following:

	Food Intake	Continuous Avoidance Behavior	
	RD 50 µmole/kg	RD 50 µmole/kg	Changes in Rate
Amphetamine	14.1	5.9	increase
Benzphetamine	52.3	>133.9	no change
Phenmetrazine	73.4	24.3	increase
Phendimetrazine	178.5	52.9	increase

a. Phendimetrazine is 3/7 as potent as phenmetrazine and 1/13 as potent as amphetamine with respect to a dose of drug required to produce a 50% decrease in food intake.

b. Phendimetrazine increased the rate of change in avoidance responding but was about 1/2 as potent as phenmetrazine and 1/9 as potent as amphetamine. The RD 50 is again the dose of drug needed to produce a 50% change in avoidance rate.

4. From the FDA report -

a) phendimetrazine (21 mg/kg) is similar to phenmetrazine (26 mg/kg) by oral administration to rats with respect to CNS stimulant activity as measured by actophotometry, but less potent than diethylpropion.

b) in toxicity studies - found dose related CNS stimulation but no tissue toxicity.

c) a few reports of euphoria were noted in the NDA.

D. Conclusions

At the present time there is in my estimation a lack of information to control this drug. Phendimetrazine is qualitatively similar to phenmetrazine (which is in Schedule II) in terms of pharmacologic profile but is quantitatively different. There is very little street abuse and there are no clinical studies to show any information on the likeability of these drugs.

The following recommendation may be made:

1. Keep an active file on this drug.

2. If clinical studies are to be done, add this drug to the list to be tested.

3. Plug the drug into the animal testing methods devised by the Biological Research Branch.

4. Decide whether a drug can be controlled from a "potential" for abuse - if the dose is high enough or if large numbers of actual case reports must be observed to schedule a drug.

5. If the drug must be scheduled now - add more weight to less important scheduling factors.

August 28, 1972

Robert P. Gerdsian, Ph.D.
Pharmacologist
Drug Information Branch

Robert V. Kasschau, Ph.D.
Pharmacologist
Biological Research Branch

Preliminary Assessment
Review of Phentermine and Benzphetamine

Attached is memo pertaining to the above subject.

Attachment

The following sources have been searched for information on phendimetrazine and benzphetamine:

NCDAI computer using generic and trade names - not listed.
Medlars.
Chemical Abstracts using chemical name - Vol. 41 - 1947 to Vol. 75 - 1971.
Index Medicus by generic names - not listed.
Toxicology Bibliography Vol. 1 (1968) to Vol. 5 #2 - (1972) - not listed.
Experta Medica - Pharmacology and Toxicology (1966 - 1971);- Psychiatry (1968 - 1971); and Public Health (1968-1971).
SCIL report for FY 71 and FY 72 - phendimetrazine tartrate #1620 - benzphetamine HCl #1230.
Poison Control Data.

The following information was found:

Phendimetrazine

marketed as Plegine by Ayerst as 35 mg. tablets NDA 12-248.
- was marketed as Dietrol by American Hygienic Co.

Poison Control Data

Code #	Drug	Age	Sex	Date	Location	Category
245848	Plegine	16	F	4/72	Maryland	2 (kick)

SCIL - 3 exhibits - see attached table.
Literature search revealed no reports of abuse.

Benzphetamine

- marketed as Didrex by Upjohn as 25 and 50 mg. tablets - NDA 12-427.
- Poison Control Data - no cases listed under trade name or generic name.
- SCIL - 14 exhibits - see attached table.
- Literature search revealed no reports of abuse.
- Letter from Mr. Van V. Pruitt, Jr. (7-26-72) confirming a sporadic movement of benzphetamine in Alabama.

At the present time, there is in my estimation a lack of information to control these two drugs. Phendimetrazine and benzphetamine are qualitatively identical to phenmetrazine and amphetamine respectively in terms of pharmacologic profile but are quantitatively different in any one test procedure. There are no clinical studies to show any information on the "likability" of these drugs.

The following recommendations may be made:

1. Keep an active file on both drugs.

2. If clinical studies are to be done, add these drugs to the list to be tested.

3. Plug these drugs into the animal testing methods devised by the Biological Research Branch.

4. Decide whether a drug can be controlled from a "potential" for abuse - if the dose is high enough or if large numbers of actual case reports must be observed to schedule a drug.

5. If the drug must be scheduled now - add more weight to less important scheduling factors.

SCIL Reports for FY 71 and FY 72

Benzphetamine

Lab. #	BNDD #	Quantity	Suspected Firm	Potency	Location	Date
05738	-	1 tab.	-	48.6 mg/ tab.	Colorado	8/12/70
06989	-	1 tab.	Upjohn	50.0 mg/ tab.	Louisiana	12/4/70
06990	-	1 tab.	Upjohn	50.0 mg/ tab.	Louisiana	12/4/70
06991	-	1 tab.	Upjohn	50.0 mg/ tab.	Louisiana	12/4/70
08441	-	40 tabs.	-	50.0 mg/ tab.	Texas	4/16/71
10940	-	2 tabs.	Upjohn	55 mg/ tab.	Texas	10/28/71

PENNWALT CORPORATION

PENNWALT BUILDING, THREE PARKWAY, PHILADELPHIA, PENNSYLVANIA 19102 • (215) 587-7000

75a

EX. I

June 8, 1973

Bureau of Narcotics and Dangerous Drugs
United States Department of Justice
Washington, D. C. 20537

Attention: William W. Vodra, Esq.
Assistant Chief Counsel

Dear Mr. Vodra:

On behalf of Pennwalt Corporation, we respectfully request that we be granted a hearing on the proposed scheduling of phentermine (our product "Ionamin") in Schedule III.

Pennwalt objects to the findings made by the Director in his proposal on phentermine (38 F.R. 12127, May 9, 1973) on the ground that:

1. The findings are erroneous as a matter of fact as not being in accord with the weight of the scientific evidence available with respect to phentermine.

2. The findings are erroneous as a matter of law.

3. The Director, in the proposed scheduling for phentermine and fenfluramine, has failed to apply the appropriate standards for phentermine and fenfluramine in determining their proposed scheduling.

It appears to Pennwalt that the Director (and the Secretary of HEW) concede an inability to document actual abuse of phentermine and therefore, in support of the proposed scheduling, presume that the absence of abuse is attributable to the "past easy availability of cheaper and more potent stimulants rather than intrinsic lack of abuse potential". (38 F.R. 12230, May 10, 1973) We do not believe that this presumption is founded in fact and submit that it is not a permissible scientific or legal conclusion.

Bureau of Narcotics and Dangerous Drugs
June 8, 1973

A primary reason for our conclusion that the potential for abuse cannot be attributed to the easy availability of amphetamine and methamphetamine is to be found in the experience in Western Germany with phentermine. There, amphetamine and methamphetamine have not been widely used nor readily available but phentermine resin has been widely used without prescription control for many years, and thus has been readily available. Nevertheless, there have been no reports of abuse of phentermine, which has been readily available through Mack in Germany. On the other hand, we are aware of no evidence of incidents, in any country, which would support the presumption by the Director (and the Secretary of HEW) quoted above from the Federal Register of May 10, 1973.

Although Pennwalt Corporation believes that all drugs in the anorectic therapeutic classification presently proposed for scheduling under Controlled Substances should be considered as a class and Pennwalt would have no objection to all members of said class being controlled under Schedule III, Pennwalt does not intend to waive its legal rights to question the basis for the scheduling presently proposed, so long as fenfluramine is proposed to be placed in Schedule IV, since such scheduling works a competitive disadvantage to Pennwalt as a result of errors of fact and law which have occurred in the investigatory process leading to the proposed scheduling.

Very truly yours,

J Gordon Logue

J. Gordon Logue
Vice President - Secretary
and General Counsel

JGL:mk

Mr. Larry Kenney, Chief, ENAE
Mr. Alfred A. Purcell, Chief, ENAH

JAN 10 1973

Kenneth A. Durrin
Assistant Director for Compliance

Impact of Reschedul[illegible] Anorectics

Attached is a self-explanatory memorandum from Chief Counsel's Office regarding anticipated FDA recommendations in connection with a number of anorectic drugs. As the memo indicates, Chief Counsel has requested that we furnish information to be used in the preparation of "an impact" statement for the Director on the manpower demands which will result from the scheduling of the listed anorectics in Schedule II and a separate appraisal on the manpower demands resulting if the same anorectics are in Schedule III.

Please study the attached memo and make a thorough appraisal of the manpower demands it will make both upon our divisions in headquarters and upon our field organization. Please supply this information to me NLT the morning of January 15, 1973 as I must have the data to Chief Counsel by the COB on the 15th.

Kenneth A. Durrin

Attachment

cc: ENA Chron
ENA subject
ENA/KADurrin/vem/3636/1-10-72

KD

DS-11

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MEMORANDUM of MEETING

SUBJECT: Control of Anorectic Drugs March 13, 1973

Attending:		
	Mr. Kerness	ENAE
	Mr. Persinger	ENAE
	Mr. Vodra	CC
	Dr. Smith	DMD
	Mr. Carabillo	SCID
	Dr. Lawrence	SCID
	Dr. Potrepka	SCID
	Dr. Zendzian	SCID

This meeting was held to coordinate BNDD's response to the HEW recommendation for control of the anorectic drugs, diethylpropion, benzphetamine, phendimetrazine, phentermine, chlorphentermine, clortermine, fenfluramine and mazindole. The latter three drugs are not yet marketed in the USA. HEW has recommended that all of these drugs be placed in Schedule III except fenfluramine which is recommended for Schedule IV.

The attendees reviewed the information presented by HEW and information presented by SCID, CC and ENA representatives.

SCID in October 1972 completed a preliminary study of the five (5) marketed drugs. The information collected at that time was not considered sufficient to justify a control recommendation but none of the information could support a case against control. Where information was available it showed that these drugs possessed qualities similar to amphetamine with possible quantitative differences.

CC and ENA have obtained preliminary information that indicates recent diversion of diethylpropion, benzphetamine, phendimetrazine and phentermine. CC presented information that some physicians were prescribing these anorectics with the express purpose of supplying stimulants, since amphetamines are not easily available. SCIL has recently received several letters from state laboratories that have identified phendimetrazine in street samples.

The information presented by HEW consisted of a summary of the information which they used to make their recommendation. While the summary information was considered insufficient by SCID it was considered to indicate that HEW (i.e., FDA) has sufficient information to justify their recommendation. Since the individuals at FDA, who contributed to the HEW recommendation,

will be utilized as expert witnesses at any required hearings, representatives of CC and SCID will interview the individuals concerned and access the quality and magnitude of the information which they have.

On the basis of the information available the attendees formulated seven options for consideration by BNDD. These options are:

1. Accept the HEW recommendations, placing all the drugs in Schedule III except fenfluramine in Schedule IV.
2. Place all the drugs in Schedule IV.
3. Place all the drugs in Schedule III.
4. Place all the drugs in Schedule II.
5. Place 4 of the drugs in Schedule III and 4 in Schedule IV.
6. Do not control the drugs.
7. No recommendation at this date, but rather dig in for more data.

Detailed outlines of the considerations for and against each option are attached. The attendees considered options #4 and #6 as unrealistic, and further that they could not justify placing fenfluramine in Schedule III and, therefore, option 3 was unrealistic. Option 7 was considered undesirable since it would require an excessive use of BNDD manpower.

As for recommending a particular choice among options 1,2 and 5, the ENA, DMD and SCID representatives considered option one as their first choice and were split in recommending between options 2 and 5. CC expressed its opinion on selecting options as follows:

> "Regarding selection of the options, Chief Counsel's office is of the opinion that action now is important for a variety of reasons. It is not crucial at this time to select between options 1, 2 and 5 (which are the most realistic alternatives) until we have commenced discussions with the drug companies and get a better feeling for the possibilities of having and winning hearings. We should enter discussions from the standpoint of the FDA recommendation in indicating a general Bureau philosophy that these drugs should be controlled "in line with FDA's recommendation." If the discussions indicate a high probability of hearings and therefore will require an extensive work-up by SCI and ENA of data now in the hands of FDA and federal, state and local agencies in the field, then we can consider other alternatives."

The Drug Control Committee's attention is directed to the need for expeditious handling of this matter. FDA is voluntarily withholding the New Drug Applications on the three new products to support our drug control efforts. The only grounds on which they can do this for any length of time is that we have commenced action to control and until that action is completed these drugs should not be made available to the American people. If BNDD delays commencing control

proceedings, the FDA position becomes untenable and they will have to permit the marketing of these three drugs. In addition the manufacturers of the five (5) presently marketed drugs are aware that BNDD has received HEW's recommendation to control their drugs and any excessive delay on our part will only serve to convince them that BDD lacks substantial evidence for their control.

Option 1 Accept HEW recommendations
(All in Schedule III except fenfluramine in IV)

Hearing Possibilities	Manf. Request	BNDD Winning
Diethylpropion	moderate	high
Benzphetamine	low	high
Phendimetrazine	low	high
Phentermine	low/moderate	high
Chlorphentermine	moderate	moderate
Clortermine	low	moderate
Mazindole	low	low/moderate
Fenfluramine	none	moderate/high

Cost of Control by BNDD

Regulatory, minimal
Criminal, low in present BNDD priorities
can be extensive if priorities change
Minimal Headquarters work-up (CC, SCID, ENA)

Pros and Cons of Option 1

Pros

rapid response
use HEW witnesses
minimize BNDD costs in scheduling
scheduling based on potential for abuse
conservative action
protect public
concur with FDA

Cons

not a serious problem now
follows FDA philosophy
uncertainty of success on 4 of 8 drugs
AMA will probably object

Option 2 Place all in Schedule IV

Hearing Possibilities

	Manf. Request	BNDD Winning
Diethylpropion	none/low	high
Benzphetamine	none/low	high
Phendimetrazine	none/low	high
Phentermine	none/low	high
Chlorphentermine	low	high
Clortermine	low	high
Mazindole	low	moderate/high
Fenfluramine	moderate	moderate/high

Cost of Control by BNDD

Regulatory, minimal
Criminal, low in present BNDD priorities
can increase if priorities change
Minimal Headquarters work-up (CC, SCID, ENA)

Pros and Cons of Option 2

Pros

IV is holding schedule (compatible with unwritten BNDD philosophy)
rapid control - no hearings
sufficient evidence for IV
will be reviewed for increased control
defensible in law and fact

Cons

back to HEW
take more time
actual diversion of at least 4 drugs
weakness in future negotiations
public disagreement with FDA
appear soft on these drugs
may require greater BNDD effort to move to II if regulatory controls were insufficient

Option 3 Place all in Schedule III

Hearing Possibilities

	Manf. Request	BNDD Winning
Diethylpropion	low	high
Benzphetamine	low	high
Phendimetrazine	low	high
Phentermine	low	high
Chlorphentermine	low	high
Clortermine	low	high
Mazindole	low	low/moderate
Fenfluramine	high	low

Cost of Control by BNDD

Regulatory, minimal
Criminal, low in present BNDD priorities
can be extensive if priorities change
Extensive Headquarters work-up (SCID & CC)

Pros and Cons of Option 3

Pros

fenfluramine has possible stimulating effects and could be unique new drug experience
scheduling based on potential for abuse
protect public (conservative approach)

Cons

back to HEW
doubtful win for fenfluramine without extensive work-up
not a serious problem now

Option 4 Place all in Schedule II
(Attendants did not consider this option realistic)

Hearing Possibilities

	Manf. Request	BNDD Winning
Diethylpropion	high	low
Benzphetamine	high	low
Phendimetrazine	moderate	moderate
Phentermine	high	low
Chlorphentermine	high	low
Clortermine	high	low
Mazindole	high	low
Fenfluramine	high	low

Cost of Control by BNDD

Regulatory, quotas, ARCOS, order forms, registration
Criminal, lower than placing these drugs in Schedule III
within present priorities
Extensive Headquarters work-up (ENA, CC, SCID)

Pros and Cons of Option 4

Pros

eliminate diversion
most effective controls

Cons

back to HEW
time consuming
excessive manpower requirements
must fight in hearings
extensive BNDD work-up required
cannot justify
AMA will object

Option 5 Place 4 drugs in III and 4 in IV
(See below)

Hearing Possibilities

Schedule		Manf. Request	BNDD Winning
III	Diethylpropion	moderate/high	high
III	Benzphetamine	low/moderate	high
III	Phendimetrazine	low/moderate	high
III	Phentermine	moderate	high
IV	Chlorphentermine	low	high
IV	Clortermine	low	high
IV	Mazindole	low	low/moderate
IV	Fenfluramine	low/moderate	low/moderate

Cost of Control by BNDD

Regulatory, minimal
Criminal, low in present BNDD priorities
can be extensive if priorities change
Minimal Headquarters work-up (CC, SCID, ENA)

Pros and Cons of Option 5

Pros

relates to actual diversion in Schedule III
holding in Schedule IV
scheduling based on potential for abuse
protect public (conservative approach)
easy to move III to II if diversion increases
easy to move IV to III if some diversion appears

Cons

back to HEW
moving from IV to II may be difficult

Option 6 — No Control
(Attendants consider this option unrealistic)

Hearing Possibilities

None

Cost of Control by BNDD

None

Pros and Cons of Option 6

Pros

None

Cons

indefensible for diethylpropion, benzphetamine, phendimetrazine and phentermine due to known diversion

public reaction

petitions to control may be expected from the public

Option 7 — No recommendation at this date

1. request further material from HEW
2. develop more information in-house
3. develop philosophy of control first

Pros and Cons of Option 7

Pros

Compels development of a philosophy

More data will be available for decision

Cons

Lose HEW assistance

Delay in control

Large BNDD work-up for small problem

Robert P. Taddeian, Ph.D.
Pharmacologist
Drug Information Branch

Judith K. Lawrence, Ph.D.
Pharmacologist
Biological Research Branch

October 24, 1972

Phentermine

Phentermine, α,α-dimethylphenethylamine, is a congener of amphetamine. It was patented in 1946 as a vasoconstrictor but is presently marketed as an anorectic. Phentermine, as the HCl salt, is marketed by Dorsey in the U.S. as Wilpo, 8 mg/tablet, in bottles of 100. A resin complex is marketed by R.J. Strassenburgh (RJS) as Ionamin, 15 and 30 mg/capsules in bottles of 100 and 400. It might be available on the U.S. market under other names since it is the subject of the following FDA New Drug Applications.

12737	8 mg	HCl salt
13082	24 mg	HCl salt
3273	5 mg/cc	methane sulfate
11513	15 and 30 mg	resin complex
16421	30 mg	resin complex

Although the following brand names do not appear in the 1972 Drug Index or Red Book they have been associated with phentermine: Duromine, Lilyl, Mirapront, and Ommibex. Possibly, they are patented names in foreign companies.

Phentermine base or its HCl salt are available as bulk chemicals from at least two companies: Aldrich Organic Chemicals, Milwaukee, Wisconsin at $19.50/100 grams and Eastman Organic Chemicals at $17.75/25 grams. (See the respective product catalogues).

A. Chemistry

Phentermine (beta-phenyl-alpha-alpha-dimethyl-amino ethane) and its amine salts are prepared by hydrogenating the corresponding beta-phenyl-beta-chloro-alpha-dimethyl-amino ethane compound in solution in the presence of a catalytic metal of the class consisting of platinum and palladium absorbed on a basic carrier such as magnesium carbonate or calcium carbonate.

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The method of preparing the precursor, beta-phenyl-beta-chloro-alpha-alpha-dimethyl-amino ethane and its amine salts, comprises mixing the corresponding beta-phenyl-beta-hydroxy-alpha-alpha-dimethyl-amino ethane compound and thionyl chloride, allowing them to react, warming, washing, and drying.

For details of the synthetic process see the attached patent.

Some of the physico-chemical properties of phentermine which might affect the absorption, distribution and excretion from the body are follows: pK_1 = 10.11; % neutral at pH7.4 = 0.19; true partition coefficient in chloroform-water-514, in heptane-water-638. (19).

3. Pharmacology

Phentermine is a sympathomimetic amine whose pharmacology, at least peripherally, depends in part or totally on the release of endogenous catecholamines. (16). Its mechanism of action centrally has not been elucidated.

1. Central Nervous System

Phentermine is a CNS stimulant. It was found to increase random activity in rats (2) and mice (9), to produce insomnia in cats (12), to produce a twittering response in chicks characteristic of amphetamine-like compounds (5), to increase the rate of continuous avoidance in rats (6) and to precipitate an acute psychotic reaction in a chronic schizophrenic. (17). It has been reported to produce insomnia and nervous irritability in some patients receiving phentermine resin complex during clinical trials. (3). Mood elevation was observed in a few patients and was reported to be comparable to that produced by amphetamine in one patient. (3).

Other indications that phentermine affects the CNS are that it is more toxic in aggregated than in isolated mice. (22); that it reverses reserpine induced ptosis (22) and that in rats it reduces food and water consumption. (13, 15). In man it is used clinically as an anorectic. (1, 14, 18).

As a CNS stimulant it is less potent than dl amphetamine. When administered orally phentermine HCl was found to be approximately 1/3rd as potent as dl amphetamine in increasing motor activity in mice (9) and 1/8th as potent in rats. (2). Administered

intraperitoneally its potency in relation to l-amphetamine was approximately 1/3rd that of amphetamine in producing insomnia in rats (12) and 1/9th in producing an increase of 50% in the rate of continuous avoidance. (6). Centrally its mode of action might be different from that of amphetamine since phentermine had little effect on reserpine induced inactivity, whereas amphetamine did counteract the sedation. (22).

2. Peripheral

The peripheral effects of phentermine are characteristic of a sympathomimetic amine of predominately indirect activity. Intravenous administration of phentermine HCl was found to produce a vasopressor response similar to that produced by dl-amphetamine. (2, 22). The drugs were equally potent.(2) and showed cross tachyphylaxis. (22). Blood pressure, heart rate and contractile force responses were produced by similar mechanisms, i.e., activation of alpha and beta receptors. (22).

As to the mydriatic potency of phentermine there appears to be a discrepancy in the literature. Holm et al (9) found phentermine to be approximately 1/3rd as active in mice as dl-amphetamine following intraperitoneal administration while Becker (2) reported phentermine to be 1.25 times more potent than dl-amphetamine.

3. Metabolism

Phentermine is more resistant to oxidative deamination than the corresponding amphetamines. (21). It is excreted almost completely in the unchanged form. (21). The urinary excretion varies greatly with the urinary pH,acidic urine favoring excretion. (4). The t1/2 for renal excretion was reported to be 19 hours after a dose of 5 mg and 24 hours after 10 mg. (20, also see 21). The t1/2 for 5 mg of d-amphetamine was found to be 7 hours in one subject and 6 hours in another. (21). Thus the duration of action of phentermine would be expected to be longer than that of d-amphetamine.

4. Toxicity

See following page.

A. Toxicity

LD_{50} mg/kg (95% confidence limits / duration)

Drug	Species	Route of Admin.	Aggregated	Isolated	Reference
phentermine	rat	i.p.	31 ± 3 mg/kg		(9)
		oral	151 (120-190)		(2)
	mouse	oral	105 (33-133)	153 (129-170)	(22)
		oral	124 (109-140)		(2)
phentermine resin complex[a.]	rat	oral[b.]	430 (216-684)[c.]		(2)
dl-amphetamine	rat	i.p.	50/mg/kg		(9)
	mouse	oral	22 (18-26)		(22)

a. Phentermine as a cation exchange resin complex of sulfonated polystyrene is marketed as Ionamin.

b. Testing procedures which required parenteral administration precluded the use of the resin complexes which were large, particulate substances; however, mice, rats, and dogs which were treatdd with toxic oral doses of phentermine resin complex were observed to exhibit identical symptoms to those seen when animals were treated with the hydrochloride salt except that the time sequence was prolonged. (2).

c. The complexing of pharmacologic agents with a synthetic ion-exchange resin reduced the toxicity of the agent. (3).

C. Information concerning the actual or relative potential for abuse of phentermine.

1. Evidence that individuals are taking the drug containing phentermine in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community.

a. A search of the Poison Control Data through 8/72 collected by Mr. Murphy revealed no record of cases involving any of the above mentioned brand names.

b. The NDA for Ionamin was reviewed by the FDA staff. It was found to contain no reports of abuse or misuse of the drug.

c. Perusal of the 6/71 thru 7/72 correspondence dealing with drug abuse retained in BNDD enforcement files revealed no correspondence pertaining to phentermine.

d. The WHO report Dependence Liability of "Non-Narcotic" Drugs listed phentermine as having an abuse potential rating of "low." (10). A rating of "low" indicates that the drug creates only mild psychic dependence and that little or no abuse has occurred or is likely to occur. (11).

e. The recent Misuse of Drugs Bill of England lists phentermine as a controlled drug of the Class C category. Other members of that category are benzphetamine, chlorphentermine, fencamfamin, mephentermine, pemoline, phendimetrazine, pipradrol and prolintane. (Misuse of Drugs Bill Schedule 2, Part III.)

f. A search of the literature revealed one case report in which phentermine was reported to exacerbate a chronic schizophrenic reaction (9), and a report of an attempted suicide with phentermine. (7). To my knowledge no other reports of abuse or misuse of phentermine appear in the literature. Thirty-

2. Evidence concerning the existence of diversion of phentermine from legitimate drug channels or that individuals are taking phentermine on their own.

a. Vann V. Pruitt, Jr., of the State of Alabama, Department of Toxicology, reported to Mr. Garfield in a letter dated 7/19/72 that phentermine was "moving" in his area but to a lesser extent than benzphetamine. Approximately one dozen exhibits had involved buys of phentermine.

b. Data obtained from BNDD cases in which phentermine was an exhibit.

Privileged: Criminal Investigation Material

Privileged: Criminal Investigation Material

SCIL identified Strassenburgh as the suspected firm in 20 of the 24 exhibits which involved drugs in dosage units. No source was identified in four exhibits. I would speculate that they were from Strassenburgh since each was made up of capsules which in three exhibits were found to contain either 15 or 30 mg of phentermine.

That Ionamin and not Wilpo appeared in SCIL exhibits might be related to the number of dosage units prescribed of the two drugs. In the National Prescription Audit published by R. A. Gosselin and Company it is reported that during 1971, 400 pharmacies filled new prescriptions with 5,736,000 15 mg capsules and 15, 736,000 30 mg capsules of Ionamin. During the same period 132,000 8 mg tablets of Wilpo were dispensed.

D. Discussion

Addition of a methyl group to the alpha carbon of amphetamine produces phentermine. This addition to the amphetamine structure is reported to reduce the CNS stimulant properties of amphetamine without altering its anorectic potency. The available data indicate that the addition of the methyl group does not significantly alter the mode of action of the drug, i.e. phentermine and amphetamine produce their effects through their actions on the catecholamine containing nerves and their end organs.

At this time it is not known if documentation of its abuse is lacking because it doesn't produce effects which are sought by drug users, or because it is less available than amphetamine or because the drug users are not aware of its pharmacology. Determination of the subject "likability" score at Lexington would help clarify if the drug is capable of producing effects which drug users seek.

Phentermine could be readily manufactured illicitly in the opinion of Dr. F. E. Anderson, after a preliminary review of the synthetic process for phentermine as reported in U.S. Patent No. 2,403,345. Dr. F. E. Anderson expressed the opinion that the precursors are commercially available and that the synthetic process is straightforward and easy to perform.

Prior to determining if phentermine was the intended product of the clandestine laboratory involved in BNDD Case NB720033 the agents and SCIL people would have to be interviewed. After perusal of the case report, I was left with the impression that the subjects had little knowledge of chemistry and failed to recognize that what they had purchased and what resulted from their manipulation was the same chemical.

E. Summary and Recommendations

1. Phentermine is an alpha methyl congener of amphetamine.

2. It is prescribed as a "non-amphetamine" anorectic.

3. The pharmacology of phentermine indicates that it has 1/3 to 1/3 the CNS stimulant potency of d or dl amphetamine and that it produces its effects through mechanisms similar to those responsible for the action of amphetamine.

4. Documentation of the abuse of phentermine is wanting.

If the intent of the Bureau is to control drugs which have been or are being abused then an active file should be kept on phentermine such that if and when it is abused it can be controlled.

If the intent of the Bureau is to control drugs which might be abused then phentermine and phentermine-resin complex should be evaluated at Lexington to determine their "likability."

cc: Dr. Floyd E. Anderson with attachments
SCI - Reading File
SCID - Reading File
SCIDM/JKLawrence/jg/10/24/72
Attachments (3)

September 21, 1972

Ernest A. Carabillo, Jr.
Chief, Drug Control Division

Robert P. Zendzian, Ph.D.
Pharmacologist
Drug Information Branch

Anorectic Agents

Preliminary review of the drugs assigned to this working group has been essentially completed and the professional opinions expressed below have been formulated. Further action requires executive decisions.

1. Dr. Lawrence will not recommend control of mephentermine, phentermine or chlorphentermine, at this time.

2. Dr. Potrepka will not recommend control of phendimetrazine or benzphetamine at this time.

3. Dr. Zendzian: At this time my recommendations remain the same, that is, the drug diethylpropion is a border line case for control. However, I am presently reviewing the extensive presentation from Merrill-National Laboratories on Diethylpropion and I have not yet formulated an opinion as to whether this will change my position. A review of this document will take about a week and I will present my thoughts then.

cc: SCI Reading File
Div Reading File
Dr. Lawrence
Dr. Potrepka
Dr. Zendzian
Dr. Anderson
Day Board File

SCID:
SCIDD:RPZendzian/mfm/x5676/9/21/72

100a

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : The Commissioner CCC
Through: Deputy Commissioner SC
ACMA

DATE: DEC 26 1972

FROM : Director, Bureau of Drugs - BD-1

SUBJECT: Scheduling Drugs of Abuse - INFORMATION MEMORANDUM

PURPOSE

This transmits information on certain problems involved in implementing the Controlled Substances Act of 1970, specifically the sections with respect to evaluating abuse potential and recommending scheduling of drugs which have medical usefulness.

This memo then describes criteria to be used in making the evaluations and recommendations and how they will be applied to the anorectic drugs presently not under schedule.

RECOMMENDED USES OF INFORMATION

This information will serve as the basis for further discussion and action in scheduling drugs, with emphasis on procedures for implementing recommendations.

TEXT OF THE INFORMATION

The Controlled Substances Act: Schedules and Control.

One of the basic principles behind the Controlled Substances Act of 1970 (CSA) is that of categorizing drugs and other substances according to their abuse potential, their medical usefulness, and their potential for producing dependence. For example, a drug should be placed in Schedule II if (a) it has a high potential for abuse, (b) it has a currently accepted medical use in treatment in the United States, and (c) abuse of the drug may lead to severe psychological or physical dependence.

The drug should be placed in Schedule III if (a) it has a potential for abuse less than the drugs in Schedule II, (b) it has a currently accepted medical use in the United States, and (c) abuse may lead to moderate or

low physical dependence or high psychological dependence. If the drug has still less potential to produce dependence or to be abused it should be placed in Schedule IV or V, or not scheduled at all. With Schedule I reserved for investigational drugs, there are five categories into which FDA-approved drugs must be placed with respect to potential for abuse and potential to produce physical or psychological dependence - Schedules II, III, IV or V, or "Schedule 0", that is, when the decision is made not to schedule at all.

The categories or schedules into which a drug is placed determine the measures which are to be taken to protect the general health and welfare with respect to the drug. These are varying control measures applied through regulations restricting the manufacture, distribution and dispensing of the drug, with compliance to be enforced by rather severe graduated statutory penalties. (The drugs in Schedule I, being investigational, require special control measures, which are not germane to the present discussion of drug scheduling.) The controls to be applied to marketed, therapeutically useful drugs are most importantly as follows:

1. For Schedule II drugs, prescriptions cannot be refilled, special order forms are required, and manufacturing quotas are allotted annually.

2. For Schedule III and IV drugs, prescriptions may be refilled five times in six months.

3. Drugs in Schedule V do not have limits on prescription.

4. There are penalties for violations of the Act which decrease from a maximum of 30 years imprisonment and/or a $50,000 fine for repeated violations with respect to drugs in Schedule II to 1 year and/or $5,000 for a first violation of Schedule V.

5. Most manufacturers, distributors, and dispensers of scheduled substances must be registered, keep accurate records and file biennial reports.

6. Package labels and inserts must carry a symbol indicating the schedule of the labeled drug.

7. Other requirements include import-export permits and special security provisions (safes) for Schedule II drugs.

It is important to note that the degree of control applied to drugs in Schedule II is considerably greater and distinctly different from the control applied to drugs in other schedules. There is a quantum leap, for example, from merely limiting a prescription to five refills in six months, to requiring a new prescription each time the patient obtains more medication. Yet the criteria for placing a drug in Schedule II are only moderately more stringent than for placing it in Schedule III. To put it slightly differently, the degree of control of a drug should be based upon the degree of risk to public health and the usefulness of the drug in medical practice. Yet the gradations of increasing risk to the public health represented by the different schedules are not paralleled by a relatively flexible and appropriate increase in control - control is very nearly all or nothing, Schedule II being so much more restrictive than the other Schedules for marketed drugs. This basic disproportion is the subject of ongoing debate, and it underlies the dilemma of those who find the legal controls associated with a given schedule inadequate to cope with the public health hazards which they believe the drug represents. Additional legislation may be required to provide control more flexibly, and consideration should be given to promoting such legislation. The intent of the Controlled Substances Act would also be enhanced by regulations which provide more precise criteria for categorizing drugs with respect to their abuse potential. In this document we are proposing such criteria as an initial step in drafting the needed regulations; until publication of such regulations these criteria could be utilized in scheduling anorectic drugs and some sedative-hypnotics.

The Controlled Substances Act: Criteria for Scheduling.

As stated above in the discussion of these schedules, the determination of the need for control depends upon the assessment of the degree of abuse potential, dependence-producing potential, and medical usefulness. The Act attempts to give some further guidance in these difficult assessments by specifying eight "factors" which are to be considered in deciding on the need for scheduling of a drug. These are:

1. Its actual or relative potential for abuse.
2. Scientific evidence of its pharmacological effect, if known.
3. The state of current scientific knowledge regarding the drug or other substance.
4. Its history and current pattern of abuse.
5. The scope, duration, and significance of abuse.
6. What, if any, risk there is to the public health.
7. Its psychic or physiological dependence liability.
8. Whether the substance is an immediate procursor of a substance already controlled under this title.

These eight factors unfortunately are for the most part vague and redundant. The list exhibits circular reasoning and lack of parallelism,

particularly when viewed together with the definitions of the schedules. Most importantly, the list of factors and the definition of the schedules leave undefined the concepts of drug abuse and abuse potential, of drug dependence, and of risk to the public health. In short, the factors provide little practical guidance in deciding particular cases. (For discussion below it should be noted that the Secretary of HEW is responsible for evaluating medical and scientific considerations, specifically, factors 2,3,6,7, and 8 - pharmacologic and other scientific knowledge, the public health question, dependence potential, and whether the substance is a precursor of another controlled substance. He is also responsible for any medical and scientific considerations involved in factors 1,4, and 5 - abuse, extent of abuse and abuse potential. Up to now this division of medical and scientific responsibilities from those of the Attorney General has been of no practical significance in making scheduling recommendations; the assessments have involved the simultaneous weighing of all possible evidence, and a DHEW - Justice consensus has been obtained.)

It has been evident almost since passage of the 1970 legislation that more specific criteria are necessary in categorizing or scheduling drugs according to their abuse potential. An attempt was made by the Bureau of Narcotics and Dangerous Drugs to devise a parametric scale of abuse potential or "Index of Harm" against which all drugs might be measured. This attempt was not successful, due to the complexity of the problems, to the lack of hard data, and to the limited number of experts.

The need to develop criteria for evaluating drug abuse potential has become more acutely apparent because of the review of the entire class of U.S. anorectic drugs, all of which are chemically or pharmacologically similar to amphetamine, the prototype CNS stimulant anorectic. This need will be brought even more sharply into focus as the degree of control required for barbiturates and other sedative-hypnotics is re-examined.

Reasons for Difficulty

Why is it so difficult to make valid determinations of abuse or dependence-producing potential? The reasons begin with the empiric recognition that it is difficult for many categories of drugs and that determinations have often been disputed. Drug dependence and abuse of types other than the morphine or alcohol - barbiturate types has been identified only relatively recently; the ways in which the more recently identified types of dependence and abuse can be quantitated are rudimentary. In more detail some further reasons for problems on categorizing drug abuse potential follow:

1. Predictive testing methodology is poorly developed and inaccurate for certain classes of drugs, so that controlled tests in animals or even humans cannot yet be used dependably for example, to determine CNS stimulant abuse potential.

2. Epidemiologic data are scanty or non-existent. Like adverse drug reaction reporting in general, reporting of drug dependence or abuse is crippled by poor case identification, lack of systematic data collection and gross or frankly inaccurate measures of incidence and prevalence.

3. Information on the risk to public health and to society constituted by different types of drug abuse is skimpy or at times purely speculation.

4. Drug dependence and drug abuse are poorly defined, and understood, as is the complex of social, economic and psychologic forces which may cause them.

Definitions and Principles

As points of departure for clarifying current procedures, the following definitions and principles are set forth. They are taken from the reports of the World Health Organization Expert Committee on Drug Dependence, probably the most authoritative body in the field - much of the CSA is also derived from their reports.

Drug abuse is defined as persistent or sporadic excessive drug use inconsistent with or unrelated to acceptable medical practice. We are here concerned with abuse of psychotropic drugs capable of producing dependence.

Drug dependence is defined as a state, psychic and sometimes also physical, resulting from the interaction between a living organism and a drug, characterized by behavioral and other responses that always include a compulsion to take the drug on a continuous or periodic basis in order to experience its psychic effects, and sometimes to avoid the discomfort of its absence.

The liability of a drug to be abused or to produce dependence is of importance for scheduling insofar as the abuse or dependence represents a risk to public health. Ways in which drug abuse may represent a public health risk are described below.

In evaluating the heterogeneous data which is associated with individual drugs, the guiding principle is protection of the public health. Thus the emphasis should be on detecting abuse and dependence-producing potential rather than actual abuse. Drugs should not be anthropomorphized as either "innocent" or "guilty". Rather, if reasonable suspicion of abuse potential exists, the drug in question should be placed in an appropriate schedule pending further data.

General Criteria for Scheduling Drugs

In establishing criteria for scheduling drugs with abuse potential the following types of data should be considered: (a) whether or not actual abuse has occurred and the availability of the drug; if abuse has occurred, the extent and type of abuse, (b) the ability of the drug to produce strong psychic dependence and, as ancillary information, its ability to produce tolerance and/or physical dependence, (c) the individual toxic manifestations which may be observed when the drug is abused, (d) close chemical and pharmacological similarity to drugs which have been extensively abused, (e) the usefulness of the drug in medical practice and the uniqueness of the drug for a particular therapeutic indication.

In utilizing the data for judging the severity of abuse potential, the following should be considered:

A. In the absence of means of predicting abuse potential, reports of abuse by humans are of primary importance. Such aspects as extent of reports in time and space, particularly epidemicity, dosage, duration, route of administration, and intensity of drug-seeking behavior are important. Data to be given heavy weight are:

1. Any epidemic, either in regions of the U.S. or in other countries, e.g., phenmetrazine in Sweden.

2. Reports of parenteral abuse.

3. Repeated reports of abuse over several years.

Because reports of abuse are not yet systematically acquired - are largely fortuitous - they only serve in the grossest way at present as indices of incidence or prevalence. Thus, considerable weight must be placed on the quality of the case reports.

1. Evidence of strong psychic dependence such as chronic ingestion, i.e., months to a year or more.

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2. Ingestion in multiples of the recommended therapeutic dose without the recommendation of a physician.

3. Obtaining prescriptions from two or more physicians within a period of time less than that for which a single prescription is intended, and

4. Obtaining drug from sources other than pharmacies; repeated reports of prescription drug purchases from pharmacies without a prescription.

5. Use of drug for euphoria or to maintain extended wakefulness provides other evidence suggesting possible psychic dependence.

B. Individual manifestations of drug toxicity when the drug is abused are of great importance in assessing the risk to public health of the drug's abuse potential.

In evaluating individual reports, to be given particular weight are:

1. Case reports documenting or strongly suggestive of toxic psychosis, e.g., delirium, paranoid psychosis, hallucinations, depersonalization.

2. Reports of marked excitation, particularly associated with assaultive or other destructive behavior.

3. Reports of marked and severely impairing alterations of mood.

4. Reports of marked social deterioration.

Evidence of illicit channels of distribution is an important, although indirect, evidence of risk to the public of a different sort, as well as evidence of abuse potential, but belongs more in the domain of the Justice Department for evaluation.

C. Particularly in the absence of clearcut reports of human abuse, the folowing data are given weight:

1. Chemical similarity to a prototype drug, e.g., amphetamines, for CNS stimulants, in association with:

Comparable therapeutic efficacy in humans, e.g., as an anorectic.

Evidence of tolerance developing.

2. Similarity of pharmacologic effects in animals to those produced by the prototype drug, e.g., for amphetamine, pressor activity, norepinephrine release.

3. Withdrawal phenomena in humans or animals, e.g., mood depression of EEG changes for CNS stimulants.

4. For CNS stimulants, evidence of self-administration in animals e.g., primates, particularly in naive animals.

5. Evidence of human "liking" or other similar subjective evaluation as tested in sophisticated subjects under blinded conditions, at varying dosages. Particular weight will be placed upon results of tests of parenteral administration.

Specific Criteria for Schedules

With respect to scheduling the following criteria will be used for the schedules indicated.

For II: 1) Epidemic abuse, current or past, U.S. or foreign,

or 2) Sporadic but clearcut abuse when great potential for individual toxicity exists, and

Sporadic but clearcut abuse when therapeutic usefulness is very limited, particularly when alternative agents exist.

For III: 1) Scanty reports of abuse under conditions other than those in II, when individual reports clearly document:

a) Chronic self- administration at multiples of the recommended therapeutic dose,

and/or b) Relatively intense drug-seeking behavior, e.g., when subjects obtain prescriptions from multiple physicians,

and/or c) The potential of the drug to be substituted for other known seriously dependence-producing drugs now under Schedule II on subjects previously dependent, e.g., subjects previously upon amphetamines succesfully substituting other congeners for amphetamines.

2) In the absence of documented cases of clearcut current chronic abuse, grounds for concluding by analogy that the drug is likely to present a risk to the public health comparable to drugs in the group under 1), above.

For CNS stimulants, such grounds include four or more of the following:

a) amphetamine- like chemical structure

b) demonstrated clinical efficacy as an anorectic

c) CNS stimulant activity in animals as evidenced by e.g.,

(i) aggregate toxicity

(ii) increased motor activity

d) evidence of development of tolerance

e) withdrawal phenomena in humans or animals, e.g., mood depression or EEG changes.

Detailed grounds for concluding by analogy that risk exists will be developed for other classes of abusable psychotropic drugs.

IV. For drugs described as analogous in III above, schedule IV rather than III is appropriate in the presence of results of tests by adequate methods indicating.

1) That the substance is not self-administered by primates.

2) That the substance is rejected in subjective evaluation of "liking" by sophisticated subjects under blinded conditions, at high dosages by the parenteral route of administration.

It is emphasized that when the predictive value of testing is better established, "analogous" drugs may be removed entirely from the schedules if testing for abuse potential is negative. But at present it is not possible to conclude an absence of abuse potential on experimental grounds. Nor is it possible to predict absence of abuse potential on the basis of claimed negative foreign experience or even claimed absence of actual abuse in the United States. Availability of cheaper alternatives, changes in controls of the prototype drugs, formulations, and modes in drugs of abuse are factors which appear to bear on abuse potential. Experience with phenmetrazine, and methaqualone, for example, has shown that our

ignorance of causes of abuse of individual drugs and our important tests make it dangerous to attempt to predict absence of abuse potential for certain classes of drugs.

V: In the current context of the Act, Schedule V is reserved for combination of small quantities of dependence-producing drugs with non-abusable active medicinal ingredients, and for combinations of depressants and stimulants with substances which vitiate abuse potential.

Drugs up for Immediate Consideration for Scheduling.

One of the matters which has brought the question of drug scheduling to a head has been the current review of anorectic drugs. It has become apparent that whereas some of these drugs have been scheduled very restrictively, e.g., the amphetamines and phenmetrazine in Schedule II, others possess abuse and dependence-producing potential, without being in an appropriate schedule.

The anorectic drugs currently not in any schedule follow below. It should be noted that with the exception of two non-marketed drugs, these have all been commented on by the WHO Expert Committee on Drug Dependence, either as possessing abuse potential or being analogous to drugs already controlled.

The drugs under consideration are:

diethylpropion
benzphetamine
phendimetrazine
phentermine
chlorphentermine
clortermine
fenfluramine
mazindole

These are recommended for scheduling in Schedule III with the exception of fenfluramine, which is recommended for Schedule IV.

In brief, these drugs are:

1) All effective anorectics;

2) Except for mazindole, all chemical congeners or amphetamines;

3) Except for fenfluramine, all CNS stimulants in animals;

4) Characterized by the development of tolerance.

Documented abuse by humans is variable, being extremely skimpy for drugs such as phendimetrazine and relatively copious for diethylpropion. It exemplifies the problems of scheduling test on chemical and pharmacologic grounds phendimetrazine appear very likely to be seriously abused, in spite of absent case reports.

The only drug for which reasonably clear test results support decreased abuse potential is fenfluramine, so that it is recommended for Schedule IV. Even here, however, the tests applied are imperfect, so that it is impossible to assert that fenfluramine will not be abused to some extent when enough subjects have been exposed to it in widespread marketing.

HES

Henry E. Simmons, M.D., M.P.H.

Prepared by: SCOVILLE 12/4/72 X34020 8D-120

cc:
OC-1
OC-2

DANBURY PHARMACAL

DFS-II
PROGRAM CODE

C1-74-0415 (GP, 64)

☒ ACTIVE ☐ CLOSED ☐ REQUESTED ACTION COMPLETED
☐ ACTION REQUESTED FROM

OTHER OFFICERS

CROSS FILE ☐ RELATED FILES

BY Joseph Vigna
AT Special Agent
DATE New York, New York
December 10, 1974

Alfred Cavuto
Special Agent

REPORT RE:
Interview of Edward PASTOR on December 9, 1974

DETAILS:

1. Reference is made to Special Agent Joseph Vigna's Report of Investigation, November 25, 1974, reflecting that a Subpoena was issued to Edward PASTOR to appear before the Grand Jury in the Southern District of New York on December 10, 1974.

2. On December 5, 1974, Edward PASTOR telephonically contacted Special Agent Vigna and advised him that he was entering the hospital on December 10, 1974 for an examination and requested that the date of his appearance before the Grand Jury be changed. Edward PASTOR agreed to come to the New York Regional Office, DEA, on December 9, 1974, in lieu of appearing before the Grand Jury on December 10, 1974.

3. At approximately 10:10 A.M., December 9, 1974, at the New York Regional Office, Special Agent Vigna, witnessed by Special Agent Alfred Cavuto, advised Edward PASTOR of his rights per DEA-13a. PASTOR stated that he understood his rights.

4. Special Agent Vigna told PASTOR that he was under investigation for illegal diversion of controlled drugs onto the illicit market. PASTOR admitted that he and Martin WEINER were partners in the illegal sale of drugs. PASTOR stated that he and WEINER bought these drugs from WINGATE SALES, Charles FERNALD, Ira SACKS, and from DANBURY PHARMACAL, and sold them on the illicit market.

5. PASTOR also stated that he and PASTOR went to DANBURY PHARMACAL to pick-up drugs, and paid cash for the drugs to either Douglas BERRY or Ira SACKS. PASTOR would only say that SACKS knew the sales were for the illicit market. PASTOR admitted paying cash to FERNALD for the drugs ordered from WINGATE with WEINER.

REGION 1, 3
DISTRICT Hartford D.O.

SIGNATURE (Agent)

APPROVED (Name and title)

DATE

Approved 12/30/74 [illegible]

DEA (Aug. 1974)

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REPORT OF INVESTIGATION
(Continuation)

FILE TITLE	IDENTIFIER	FILE
DANBURY PHARMACAL	DPS-II [illegible]	CI-[illegible]
	PROGRAM CODE	

6. PASTOR indicated that he would cooperate with the government. Special Agent Vigna advised him that his willingness to cooperate would be discussed with the U. S. Attorney's Office. PASTOR was not made any promises concerning his pending criminal charges.

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DANBURY PHARMACAL | DF5-11 | C1-74-0115 (CP. 4)

DF511

[X] ACTIVE [ ] CLOSED [ ] REQUESTED ACTION COMPLETED
[ ] ACTION REQUESTED FROM:

BY Joseph Vigna
AT Special Agent
DATE New York, New York
April 8, 1975

OTHER OFFICERS: Harry P. Weinkauff, Group Supervisor

NOTE FILE | RELATED FILES

REPORT RE: Interview of Edward PASTOR on February 26, 1975

DETAILS:

1. Reference is made to Special Agent Joseph Vigna's Report of Investigation, dated December 10, 1974, reflecting PASTOR'S interview on December 9, 1974.

2. At approximately 10:00 A.M., February 26, 1975 at the New York Regional Office, PASTOR was interviewed concerning his involvement in the diversion of controlled substances from WINGATE SALES, New York, New York and DANBURY PHARMACAL, Danbury, Conn. Prior to the interview Special Agent Joseph Vigna, witnessed by Group Supervisor Harry P. Weinkauff, advised PASTOR of his rights per DEA-13a. PASTOR stated that he understood his rights. PASTOR was questioned on the particulars of the transactions between himself, Martin WEINER, Ira SACKS and Charles FERNALD. PASTOR gave evasive and very general answers and attempted to minimize his role in the conspiracy. At approximately 11:30 A.M., the interview was terminated.

SIGNATURE (Agent) Joseph Vigna
Joseph Vigna, Special Agent
APPROVED Harry P. Weinkauff
Harry P. Weinkauff, Group Supervisor
DATE 4/10/75

-6
wmh 4/10/75

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Interview of

P = Pasteur

JV = Joseph Vigna, Special Agent

HW = Harry Weinkauff, Group Supervis

JV How did you first meet Mr. WEINER

P Seven years ago, down at the Shore.

JV The Jersey Shore?

P Florida

JV

P We were in the same business market. We would buy he would supply which would be from Applebaum

JV Genex, Hollywood, Florida.

P Yes

U.S. DRUGS

JV Down in Florida he was your ?

HW for what?

P Stolen merchandize

JV How did you meet Dr. JOHNSON

P Thrity years ago

JV

P A doctor I met named Eric CLARKE was in practice in New Jersey.

JV CLARKE is black

P Yes

JV How did you first buy P for the Wingate sale?

P I would know when be bought P

JV Would you show invoices to Parker for P?

P Who packaged those pills?

JV That is what I want to know from you.

P

I knew their shipping

JV Why?

JV Are some of them marked by the shipping clerk?

P That I am sure is true.

JV Where were the packages going? Viternin

P. The Vitarin has been out of business for years, are you aware of that?

JV I am aware of that

JV Have you ever money for dealing

P It was given to me by Mr. WEINER

JV

P It was an envelope I am sure it was money

JV Teletype check?

P He was trying to price an item a Memo the i. tial merchant. WEINER was in

P I was in Fenabarbital.

JV He was at your table and he was Barry steal them and give them to

WEINER

JV

P

JV The last time we spoke you and WEINER were

P

JV 50-50 Partnership

P No

P The merchandise that I shipped for WEINER was not P

JV The last time we spoke you told us that you _____

P They were your

JV instead of WEINER

P. They were by truck at Danberry I was to fly down to Philadelphia

or to Clement Airport

JV Where to then

P New Jersey. Last Westchester, Whiteplains.

JV The last time I spoke to you you said you would be able to

P

JV

P He would be the middle man. I was not introduced to him.

JV How much _____

JV I know you of those pills two weeks after the_____

P

JV Talk to Dr. Johnson to for you

P No

JV Did you ever

P No reason to

JV to Days to prepare the deal. Were you paid in cash

P I was thrown an envelope, I take it that that was cash

HW

JV

P

JV Who is Ira? Was Ira

...at the ...

How did he know?

Class II, III Controlled Substances Manufacturing license.

You were manufacturing I

How did he know that these classes , how did he know they were going to the illegal market? He was categ

It is not a legal transaction it would be 28,000 tabs. I have not seen a

OK

Then I was paid a sum and not at another

the times you were paid

HW What was the price

JV I am asking you/ Lets take a transaction that you might How did you always know? After Westchester how did you get to

P I was asked to fly

HW Where?

P to for merchandise

JV

P I would have to be

JV At the Airport did Ira go or to the firm

P Both

Would he be the with them?

P Which were unmarked and I would fly

JV At that time the _____

P

JV Ira never chose the meeting place

P No _____

HW Where is the meeting place

P It is hard to recall. It is hard to recall. There were many

JV About the met. I know we decided the Airport

P at the

JV The Airport

P _____

JV At the Airport

P

P The place that Weiner

JV

P He was

JV

JV

P NO

JV

P

JV

P

JC Did you sever see a Bill of Laiding.

P No

JV No?

Weiner

P No I do not recall

V

JV did your read this letter

P

C that and to you?

P.

JV Dr. Johnson

P

JV

P. I have seen it in the past

JV How much money was do you recall that

P

JV Where was the money

P At the Pennsylvania Station

JV

P I do not recall Airport at the

HW Which Airport

P Philadelphia

JV Will you be able to

P

JV

P

JV You

P I woudl know that it had white and black specks tablet

HW You saw it?

P by the size give to Wally Weiner

JV Hand deliver

P Hand deliver

I was going to you it was a Chevorlet, 4 door sead, yellog

HW It met you

P Pennsylvania Plates

P

HW

P

W

O

JV

P

JV

P

JV

P I dont know Three men 2 had medium builds

JV

P

I package It was an odd size package part of the total shipment.

JV Did you ever

JV

P

JV

P

JV to where

P That was shipped to Tri State

JV to Tri State

JV Bolar in Long Island

P Bolar in Long Island, I don't know them but I have seen their merchand.se by the

JV

P

JV

P

JV

P

JV

122a

P

P

P Did Parker have a Bill of Laiding

JV With Tri State

JV Why

where did it go?

P I am not sure

HW We are talking of the past

P I am talking of the past

JV Do you think you will be able to with the _____

HW

P

HW How much

P That I don't know A Million of a Million and a half

JV

P Port Washington

JV

P

JV Port Washington is a suburb of Philadelphia

P Just outside of Philadelphia

JV If you are going to fly?

P

JV Was Mr. WEINER in debt

P Tremendous debt

P $600,000.00

JV to who

P Bill WALL

JV Who is Bill WALL

P

HW What was the money for

P To

JV Men in Philadelphia

P

JV

P Baba

He was

JV

P

P

JV

JV How old

P 59 years old

JV Who

P Who

JV Business Trip

P

JV

P

J

JV

P Yes

JV Have you even met Baba

P Yes

JV How

P I met Baba through a friend named Joe Wa he was a business partner with Baba

HW Why

P I have a reason , ... two days before he was killed he $7000 to Baba and the _____ Pay off and was paid off with a bullet in the brain. It is a dangerious business, Very Dangerous

JV Mr. Weiner

P Baba did not 134 Market Street

JV

P

J.

P

JV

P Yes

JV _____ _____Chevrolet Baba is

HW

P

JV

P Yes

JV

P

JV

P

P

HW

P

JV

P

meet the "main man" Tuesday evening (September 10, 1974)

THE HAHNEMANN MEDICAL COLLEGE & HOSPITAL OF PHILADELPHIA
TWO-THIRTY NORTH BROAD STREET PHILADELPHIA, PENNSYLVANIA 19102

DIVISION OF NEPHROLOGY AND HYPERTENSION

September 25, 1975

Mr. Richard H. Kuh
Kuh, Shapiro, Goldman, Cooperman, and Levitt
800 Third Avenue
New York, New York 10022

Dear Mr. Kuh:

Mr. Edward Pastor was hospitalized at Hahnemann Hospital from March 19, 1966 to April 30, 1966 for an acute myocardial infarction.

He sustained a second attack on July 5, 1966.

Following these two episodes, he was put on long-term anticoagulant therapy and coronary dilators. Recurrent episodes of angina continued.

From March 22, 1967 to April 6, 1967, he was hospitalized at the Pennsylvania Hospital for another myocardial infarction.

Since that time, he continued to have symptoms of coronary insufficiency.

During the years, 1973-1974, angina attacks continued and became more severe.

On October 2, 1974, he was hospitalized again at the Hahnemann Hospital for crescendo angina and impending myocardial infarction. It was our opinion that although the angina was severe, no infarction had occurred at that time.

After discharge, it became evident that Mr. Pastor was developing essential hypertension with hypertensive cardiovascular disease, and he was treated with diuretic and propranolol.

During the month of September, 1975, his precordial pain increased and was present both at rest and during exercise.

On September 11, 1975, Mr. Pastor was hospitalized at the Hahnemann Hospital again as an emergency, because of unstable crescendo coronary insufficiency. He was admitted to the coronary care unit. Serial electrocardiograms revealed severe coronary artery disease.

Cardiac catheterization was performed which demonstrated a complete occlusion of the right coronary artery. In addition, there was an occlusion of the left coronary artery with the lower segment of it vascularized by collateral circulation. There was evidence of severe damage to the left ventricle with hypokinetic ventricular contractions.

The diagnosis at this time is advanced, irreversible coronary artery disease, with crescendo angina and impending myocardial infarction with severe myocardial insufficiency.

The patient has been put at limited activity and heart surgery is considered within the next 4-5 months if the clinical picture stabilizes. The prognosis is extremely serious.

If there are any questions, or if I can be of any further help, please do not hesitate to contact me.

Sincerely yours,

Gaddo Onesti

Gaddo Onesti, M.D.
Professor of Medicine
Department of Medicine

GO:rr

127a

THE HAHNEMANN MEDICAL COLLEGE & HOSPITAL OF PHILADELPHIA
TWO-THIRTY NORTH BROAD STREET PHILADELPHIA, PENNSYLVANIA 19102

DIVISION OF NEPHROLOGY AND HYPERTENSION

November 6, 1975

Richard H. Kuh, Esquire
Kuh, Shapiro, Goldman, Cooperman, & Levitt
800 Third Avenue
New York, New York 10022

Dear Mr. Kuh:

In answer to a request of the clinical condition of Mr. Edward Pastor, I can now add the following information on his therapeutic regimen.

Since October, 1972, Mr. Pastor has received daily treatment with:

1. propranolol
2. Dyazide
3. isosorbid dinitrate
4. chlordiazepoxide
5. phenobarbital
6. clobiferate
7. meprobamate

Some of these drugs, used alone, but particularly when used in combination, result very frequently in loss of mental alertness, drowsiness, disorientation and mental confusion.

I hope this information will be useful to you. If you have any further questions, please do not hesitate to call upon me.

Sincerely yours,

Gaddo Onesti

Gaddo Onesti, M.D.
Professor of Medicine

GO:rr

JWT:sr
75-2637
M-910

October 8, 1975

Richard H. Kuh, Esq.
Kuh, Shapiro, Goldman, Cooperman
& Levitt, P.C.
800 Third Avenue
New York, New York 10022

Re: United States v. Pastor and Weiner,
75 Cr. 753

Dear Mr. Kuh:

I have your September 26, 1975 letter to me, together with your October 2, 1975 letter to Judge Motley. I appologize for not answering your September 26 letter earlier. However, as you know, I am on trial.

Your September 26, 1975 letter sets forth several reasons why you believe the Government should join defense counsel in requesting that Judge Motley extend the time for defense motions in this case. As you will see from the following, the Government has provided, or will shortly provide, all answers and materials that it appears you genuinely need to make your pre-trial motions. Accordingly, I see no reason for the Government to join in an application to extend the time for the defendants to make their motions.

Rec'd 10/10/75-5:15 pm NO Enclosures!

JWT:sr
75-2637
1-910

Your request would require the Government to turn over

Points 1 and 7 of your letter ask that the Government turn over Brady materials before the defendants make their pretrial motions, so that the defense may move for any materials they believe they are entitled to receive under Brady, but that the Government does not voluntarily turn over Brady materials more than three months prior to trial. Absent certain unique circumstances, there is no requirement that Brady material be turned over prior to trial. I know of no material in this case that must be turned over before trial. Accordingly, I believe that your request for Brady materials at this early stage of the case is premature.

However, the Government does undertake to voluntarily turn over any Brady materials sufficiently far in advance of trial so that you will have adequate time to make the use of them to which you are entitled.

Point 1 in your letter also requests that the Government turn over Rule 16(b) materials prior to the defendants' pre-trial motion, so that the defendants may know whether they need to make a Rule 16(b) motion. At our September 22 meeting I promised to turn over all the Rule 16(b) materials that you requested. Accordingly, I do not believe there is any dispute between us on this point, and I don't believe you will need to raise this point in your motion.

In Point 2 of your letter you request a bill of particulars stating where certain events occurred in order to make a venue motion. I believe that this request is reasonable and I will prepare such a bill this week-end. (In passing, I believe your letter errs in indicating that I agreed to give the names of persons who were present at the time various actions took place.)

Point 3 in your letter is answered by copies of your client's statements which are enclosed. Points 4 and 6 are answered by my September 22, 1975 letter. (Due to an administrative mix-up in this office, this letter was not mailed until after September 22 and probably had not been received by you when you wrote your September 26 letter.)

JT:sr
-910r

Point 5 of your letter assumes that the Court will look beyond an indictment and examine the strength of the Government's evidence in a pre-trial motion. Since I do not believe the Court will do this, I do not believe it necessary to provide the materials you request in this Point.

In summary, the Government declines to join in your request for an extension because the Government has provided, or will shortly provide, all answers and materials that it appears you genuinely need to make your pre-trial motions.

Finally, your October 2, 1975 letter to Judge Motley states that you have not yet received the materials that Judge Motley directed the Government to turn over by September 26. As I informed you in my September 26, 1975 letter, these materials were mailed to me from Washington, D.C. on September 25. However, I have not yet received the materials. Today, I initiated new inquiries to determine what has happened to them. As soon as I receive the materials, they will be forwarded to you.

Very truly yours,

PAUL J. CURRAN
United States Attorney

By: John Timbers
JOHN TIMBERS
Assistant United States Attorney
Telephone: (212) 791-1984

cc.: Honorable Constance Baker Motley
United States District Judge
United States Courthouse
Foley Square
New York, New York 10007

W. Donald Sparks, Esq.
Legal Arts Building
Front and Leman Street
Media, Pennsylvania

United States Department of Justice

ADDRESS REPLY TO
"UNITED STATES ATTORNEY"
AND REFER TO
INITIALS AND NUMBER

JT:ccc

75-2637

UNITED STATES ATTORNEY
SOUTHERN DISTRICT OF NEW YORK
UNITED STATES COURTHOUSE
FOLEY SQUARE
NEW YORK, N. Y. 10007

September 22, 1975

Richard Kuh, Esq.
Kuh, Shapiro, Goldman, Cooperman
and Levitt, P.C.
800 Third Avenue
New York, New York 10022

W. Donald Sparks, Esq.
Legal Arts Building
Front and Leman Streets
Media, Pennsylvania

Re: United States v. Edward Pastor,
75 Cr. 7533 (C.B.M.)

Gentlemen:

This letter is written to confirm our discussion this afternoon about discovery in this case.

On behalf of the Government I agreed to supply the following:

1. copies of all written and recorded statements made by your clients to representatives of the Government after commission of the crime, and the substance of any oral statements by your clients to Government representatives after commission of the crime, which the Government intends to offer at trial;

2. relevant documents within the possession, custody, or control of the Government on which the Government will rely;

3. FBI fingerprint records showing your clients' criminal records;

bc'd 10/3/75 by mail

JT:rs
75-2637

4. a bill of particulars giving the date, time and place of occurrence for each of the overt acts listed in Count One of the indictment and for the crimes specified in Counts Two through Five.

During our discussion I informed you that the Government did not utilize any electronic surveillance or wiretap in connection with this case. In addition, I undertook to determine whether the Drug Enforcement Administration or United States Attorney's Offices in Manhattan or Philadelphia, Pennsylvania have used electronic surveillance or wiretaps on your clients in any connection; (2) since the phendimetrazine and phentermine in this case were never seized by the Government there are neither samples nor lab reports; (3) the Government will supply Jencks Act material and any criminal record of a Government witness at the beginning of the day on which that witness is expected to testify, unless this material is so extensive that it cannot be digested in the time prior to cross-examination of the witness -- in which case the material will be supplied earlier.

Finally, the Government agrees to the taking of Dr. Horace Johnson's deposition prior to trial, provided that the deposition is conducted under the supervision of a Magistrate or other court officer.

Very truly yours,

PAUL J. CURRAN
United States Attorney

By: John Timbers
JOHN TIMBERS
Assistant United States Attorney
Tel. No. 212-791-1984

JT:rs
75-2637

cc: Hon. Constance Baker Motley
United States District Judge
United States Courthouse - Foley Square
New York, New York 10007

UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

In the Matter of:

The Proposal to place the drug PENTAZOCINE in Schedule III of the Comprehensive Drug Abuse Prevention Control Act, (P.L.91-513, 21 USC 801 et seq.) PENWALT CORPORATION.

Docket No. 73-15

East Court Number 1
1111 Constitution Avenue, N.W.
Washington, D. C.

Monday
December 10, 1973

The further pre-hearing conference in the above-entitled matter commenced at 11:10 A.M. before THE HONORABLE WILLIAM E. BRENNAN, Administrative Law Judge.

APPEARANCES:

On behalf of Drug Enforcement Administration:

JAMES A. ROSEN, Esq.
WILLIAM W. VODRA, Esq.
RICHARD I. LEDOVITZ, Est.

On behalf of Penwalt Corporation:

JAMES M. JOHNSTONE, Esq.
JON PAUGH, Esq.

1776 K Street, N.W.
Washington, D. C. 20006

BEST COPY AVAILABLE

without discussion.

The Government, in brief and in argument -- first argument -- cites Section 201(c) as a basis for the exercise of the Administrator's discretion basically, the eight enumerated factors which [illegible] the Attorney General or the Administrator to consider in making the necessary findings for control or non-control under the Act.

I do not read Section (c) as a grant of discretionary power; I read it as a limitation of discretion, because the Attorney General -- the Administrator, in fact, must be sure he considers the eight elements which are listed.

Now certainly, if the Government means, by the use of the word "discretion" a liberty or a freedom to assign different weights to the factors set forth in Section 201(c), I would be inclined to agree with that analysis. But I do not read Section 201(c) as a grant of discretionary power.

During argument and consideration of the briefs, I have become concerned with what appears to be the practice of the Administrator to allow interested parties which may have a drug being proposed for scheduling to comment to the placement of the proposed drug on a certain schedule. I see no [illegible] for such an action in the Act; I think the Act is clear. I think the Administrator must make the finding set

factors which the Administrator must consider. Congress has not stated that equal weight to every such factor of the eight must be assigned, but the Administrator must consider those factors, and after a consideration of those factors, plus the recommendation of the Secretary of HEW as it relates to scientific and medical evaluations, then the Administrator must compare the evidence that he has on a proposed drug with the evidence he has used and upon which he has concluded to place drugs in Schedules 1 through 5.

I am persuaded by Penwalt's arguments, but for the availability of comparative information as to drugs proposed for scheduling. As a matter of logic, because I am unable to find anything in the Act or the legislative history going to the point, I find it inconceivable that Congress intended to give an interested party the authority to look at data which the Administrator is currently considering in following the mandates of the Act and arriving at an ultimate decision, which he has not arrived at, as to whether to schedule a particular substance, and what particular Schedule the substance should be listed on.

So I do not think that as far as even discovery is concerned, that Penwalt was persuaded in that they have a right to comparative information on the proposed drugs.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA	:	AFFIDAVIT
-v-	:	75 Cr. 753 (CBM)
EDWARD PASTOR and MARTIN WEINER,	:	
Defendants	:	
STATE OF MARYLAND	)	
	:	ss.:
COUNTY OF MONTGOMERY	)	

WILLIAM W. VODRA, being duly sworn, deposes and says:

1. I am Associate Chief Counsel for Drugs of the Food and Drug Administration, (hereinafter "FDA"), United States Department of Health, Education and Welfare (hereinafter "HEW").

2. I submit this affidavit in opposition to that part of the defendant's omnibus pre-trial motion that seeks to dismiss the indictment. Specifically, I submit this affidavit in opposition to that part of defendant's motion to dismiss that alleges that the Attorney General did not consider the eight factors specified in 21 U.S.C. §811(c) when he directed that phendimetrazine and phentermine be placed in Schedules III and IV, respectively.

3. I was an attorney in the Office of Chief Counsel, Bureau of Narcotics and Dangerous Drugs (hereinafter "BNDD"), United States Department of Justice, from 1971 to 1974. From 1972 to 1974 my title in that office was Assistant Chief Counsel.

4. In 1971, I was responsible for the drafting and promulgation of the regulation (now codified in 21 CFR Parts 1308 and 1316) governing the procedures and requirements for scheduling, rescheduling, and decontrolling substances, pursuant to sections 811 and 812 of Title 21, United States Code. Subsequently, I participated in gathering information and giving legal advice in connection with the 1971 transfer of amphetamines and related substances from Schedule III to Schedule II; the 1972 transfer of certain barbiturates from Schedule III to Schedule II; the 1972 placement of certain hallucinogens in Schedule I; the 1972 transfer of etorphine from Schedule I to Schedule II; and the 1973 placement of methaqualone in Schedule II; as well as the rescheduling of phentermine, phendimetrazine, and six other anorectic drugs in 1973. As a result of this experience, I was, and still am, familiar with the procedures followed by the Attorney General and his delegates in placing drugs in the schedules set forth in 21 U.S.C. §812.

5. The Attorney General has delegated his power to schedule drugs to the Director of the BNDD. From 1968 to June 30, 1973, the BNDD Director was John E. Ingersoll.

6. Section 811(c) of Title 21 specifies eight factors that the Attorney General or his delegate must consider when scheduling a drug. Section 811(b) specifies that the Secretary of HEW shall evaluate those factors in Section 811(c) that are scientific and medical in nature, and that the HEW Secretary's recommendation on scientific and medical factors shall be binding on the Attorney General. The HEW Secretary has delegated his power

further delegation

to evaluate and make binding recommendations on the scientific and medical factors in a scheduling proposal to the Assistant Secretary for Health. (21 CFR 2.120).

7. From 1971 to 1974 the BNDD Director made his decision to schedule a drug after receiving oral and written presentations from a committee appointed to evaluate the proposal. Members of such a committee would represent those parts of BNDD whose work concerned collecting and evaluating data relevant to the criteria set forth in 21 U.S.C. §§811 and 812. Generally, several members of a committee would represent BNDD's Office of Scientific Support, in particular, its Drug Control Division ("SCID"), whose function was to analyze pharmacological aspects of the drug considered for scheduling and to receive and evaluate reports of the drug's abuse that were generated by the medical community. Other medical evaluation of a scheduling proposal was provided to committee by BNDD's Chief Medical Officer. Also represented on a committee would be the BNDD Office of Compliance ("ENAR") which was concerned with appraisal of the diversion and illicit traffic in legitimate drugs. A representative of the BNDD Chief Counsel's office on the committee would supervise legal aspects of the scheduling proposals.

8. I represented the Chief Counsel's office on the committee that advised the BNDD Director about the 1973 scheduling proposal for anoretic drug products (i.e., products used for weight reduction in the treatment of obesity), including phendimetrazine and phentermine.

9. During early 1972, HEW-FDA informally notified BNDD that HEW-FDA was engaged in a major review of all anorectic drug products. Late in 1972, HEW-FDA orally advised BNDD that HEW-FDA might recommend that the Attorney General place certain anorectic drug products under controls provided by 21 U.S.C. §812. In December, 1972, representatives of the FDA testified before the Subcommittee on Monopoly of the Senate Judiciary Committee about the HEW-FDA's anorectic drug review. In this testimony, HEW-FDA representatives announced that HEW-FDA had completed the most thorough, extensive, and comprehensive review of any class of drug products ever undertaken by HEW-FDA, including 206 scientific studies involving over 9,000 human subjects and related animal studies. The results of this study, were contained in 1,100 volumes of data. HEW-FDA, working with an advisory group of non-government medical experts, concluded that the drugs had limited but positive effectivenss in weight reduction. HEW-FDA also announced that it would recommend placement of most of the unscheduled prescription anorectic drugs, including phendimetrazine and phentermine, in Schedule III of 21 U.S.C. §812. At this same hearing, members of the independent group of experts testified that they had advised FDA to recommend placing all anorectics in Schedule II.

10. Upon learning about the HEW-FDA scheduling proposal, the committee to advise the BNDD Director about this proposal commenced reviews, through various BNDD units, of data and information available to them on unscheduled anorectic drug products. Thus members of BNDD's SCID Unit

conducted preliminary studies of scientific and medical aspects of some of the anorectic drugs being evaluated by HEW-FDA so that those SCID members could familiarize themselves with the drugs, in case HEW-FDA should recommend that the Attorney General place these drugs on schedules. The SCID staff members familiarizing themselves with anorectic drugs did not have access to much of the raw data regarding drug safety that FDA was using in its study because FDA considered this information to be a trade secret information that was barred from disclosure by 21 U.S.C. §331(j). Accordingly, the staff members did not do a full work-up on the drugs they were studying, and the SCID staff did not attempt to formulate a staff position on the scientific and medical aspects of these drugs. In general, the familiarization studies by SCID staff members were inconclusive, and the scientists conducting the studies felt that the information available to them was insufficient to justify a recommendation for control or to support a recommendation against control.

11. In early 1973, HEW-FDA published in the Federal Register a notice of its findings on the effectiveness of anorectics. (Federal Register, Vol. 38, No. 28 - Monday, February 12, 1973: annexed hereto as Exhibit 1).

12. In February HEW-FDA recommended to the Attorney General that seven of the anorectic drugs (including phendimetrazine and phentermine) considered by the HEW-FDA in its efficiency studies be placed in Schedule III. (February 15, 1973 letter from Richard L. Seggel, H.E.W. Acting Assistant Secretary for Health, to John E. Ingersoll, Director, BNDD: annexed hereto as Exhibit 2). Attached to

HEW-FDA suggested might be of "possible utility" to BNDD and "a basis for further discussion."

13. The HEW-FDA recommendation was made pursuant to 21 U.S.C. §811(f) which authorizes the HEW Secretary to notify the Attorney General when a new-drug application made to the HEW-FDA concerns a drug that has a stimulant, depressant or hallucinogenic effect on the central nervous system. (An alternate procedure for commencing the scheduling process is set forth in 21 U.S.C. §811(b) which authorizes the Attorney General to initiate scheduling proceedings after requesting that the HEW Secretary make a scientific and medical evaluation of the drug and after requesting that the Secretary give his recommendation about whether, and how, the drug should be controlled.)

14. After the HEW Assistant Secretary's February 15, 1973 recommendation was received, BNDD staff members assembled information about abuse, and the potential for abuse, of the drugs recommended for scheduling. This information showed that in the short time since amphetamines had been placed in Schedule II in 1971 unscheduled anorectic drugs, including phendimetrazine and phentermine, were increasingly becoming the subjects of criminal drug traffic. From the drug abuse information gathered by the committee, it appeared that the anorectic drugs were being used by drug users to replace amphetamines, which had become more difficult to obtain since they had been placed in Schedule II. Examples of information showing this trend included: Law enforcement officers in Texas reported recent investigations involving criminal trafficking in phentermine and phendimetrazine by physicians. Other states reported the increasing appearance

of phendimetrazine and phentermine in illicit traffic, and several wholesalers and retailers reported phentermine thefts in situations that indicated that the purpose of the theft was criminal distribution or abuse of the stolen drug. Truck drivers appeared to be taking phentermine for non-medical purposes. Experimental use among members of the "Drug culture" was being noted with greater frequency. One such drug abuser reported that she and her colleagues considered phentermine to be a "raunchy" substitute for speed -- to be taken only when speed was not available because phentermine was a "bummer." Drug treatment programs reported that phentermine now had a street name, also suggesting that phentermine was becoming very familiar in drug abuse circles. (Memoranda recording BNDD staff analyses of abuse, and the potential for abuse, of phendimetrazine and phentermine are annexed hereto as Exhibit 3.)

15. The apparent substitution of unscheduled anorectic drugs including phentermine and phendimetrazine, for amphetamines and phenmetrazine in late 1972 and early 1973 corroborated HEW-FDA medical and scientific findings about the close similarity of all of these drugs in chemical structure and pharmacological profile. Nevertheless, the BNDD SCID staff members who had conducted the preliminary familiarity reviews of the unscheduled anorectic dru (described in paragraph 10 above) were not satisfied by the February 15, 1973 HEW-FDA recommendation letter and the attached materials, which they felt were not sufficient standing alone to support a scheduling proposal. This matter was discussed on March 13, 1973 at a meeting of the committee appointed to evaluate the scheduling of anorectic

drugs. Believing that the very extensive review which HEW-FDA had conducted must contain considerable relevant data which had not been supplied to BNDD, the committee decided to return to HEW-FDA to determine whether HEW-FDA did indeed have additional data which would justify findings by the Director that the drugs were sufficiently similar to amphetamines to warrant scheduling.

16. In the middle of March, 1973, HEW-FDA supplied scientific and medical documentation about the scheduling proposal. This documentation supplemented the materials that had been attached to their February 15, 1973 recommendation. (The materials to the February 15, 1973 letter are annexed hereto as Exhibit 4. The supplementing materials received by BNDD in Mid-March 1973 are annexed hereto Exhibit 5). Then, late in March, Dr. Robert Zendzian of SCID, Dr. Robert Potrepka, also of SCID, and I met with the HEW-FDA officials who participated in the HEW-FDA efficacy study of the anorectic drugs proposed for control. We discussed the full range of HEW-FDA documents and testimony which HEW-FDA possessed on the scientific and medical aspects of all anorectic drugs. Based on these interviews and document analyses we concluded that these witnesses and documents did provide scientific and medical information that would clearly be sufficient to support a determination by the Director to schedule the drugs, as recommended by the Assistant HEW Secretary for Health.

17. On April 3, 1973, BNDD Director Ingersoll met with the anorectic drug scheduling committee and other staff members who had assisted in gathering and evaluating material for the decision on the HEW-FDA proposal. At this meeting, representatives of each BNDD office involved, made an oral presentation of the data his office had gathered and evaluated. The Director had in front of him an

April 2, 1973 memorandum with attachments, prepared by me, but no other documentary presentation was made. (The [illegible] is annexed hereto as Exhibit 6).

These oral presentations specifically included the March 30 interviews with HEW-FDA officials, regarding the available evidence on the pharmacological effects and other medical and scientific aspects of the drugs. The staff also reviewed, for the BNDD Director, information regarding abuse patterns and the significance of the abuse. Particularly emphasized were the parallels between the current situation with the marketed, unscheduled anorectics, such as phendimetrazine and phentermine, and the early appearances of amphetamine abuse in the United States. The Director was also presented with an assessment of the impact on BNDD resources of regulating the unscheduled anorectic drugs.

18. At the conclusion of the April 3 meeting, the BNDD Director found that there was not sufficient evidence to justify the Director placing the unscheduled anorectic drugs in Schedule II, but that evidence was sufficient to justify placing the drugs in Schedule III. The Director also determined that he was not willing to commit considerable BNDD resources to protracted litigation over the scheduling of these drugs. Mr. Ingersoll therefore directed me to meet with manufacturers to determine their response to scheduling the drugs.

19. During the next month I met with manufacturers of the anorectic drugs that the Director had determined should be scheduled. I explained to the firms that, after reviewing potential for abuse, medical and scientific information, the Director was prepared to follow through on

the HEW-FDA's recommendation to place the anorectic drugs in Schedule III, unless the manufacturers could present evidence as to why their individual drugs should not be scheduled. Only two manufacturers returned information in response to my presentation. In fact, the information submitted by these two manufacturers was already in the HEW-FDA files and had been considered by the HEW Assistant Secretary in making his recommendation.

20. On May 1, 1973, the Director signed notices of proposed rulemaking for eight unscheduled anorectic drugs. (The notices for phendimetrazine and phentermine are annexed hereto as Exhibit 7). Since these two notices are substantially similar, this affidavit will discuss only one of the notices in detail - the phendimetrazine notice.

21. In the phendimetrazine notice the BNDD Director recited the materials that the committee had reviewed and on which it had reported to him. The Director then stated the conclusions that he had drawn from the committee's presentation.

> "(1) Phendimetrazine is chemically similar to and related to the other anorectic drugs being proposed for control, and to the amphetamine, methamphetamine, and phenmetrazine substances currently listed in Schedule II.
>
> "(2) Phendimetrazine has a pharmacological profile which is similar to the other anorectic drugs being proposed for control and to amphetamine, methamphetamine, and phenmetrazine. This general similarity suggests that all of these drugs may be reasonably substituted for each other for therapeutic or abuse purposes.
>
> "(3) Phendimetrazine is covered by a new drug application approved the Food and Drug Administration for use in treatment of obesity.

at Time of alleged conspiracy drugs not under Control

"(4) Products containing benzphetamine, chlorphentermine, diethylpropion, phendimetrazine, or phentermine have been marketed in the United States for several years. In the last 6 months, certain of these products have been reported as the subject of thefts, diversion, illicit sales, and abuse. Quantitatively, this data does not suggest a widespread problem at the present time; qualitatively, the data indicates a trend to methamphetamine in abuse circles. This reinforces the belief that abuse of the pharmacologically similar drugs will increase as the amphetamines and methamphetamine become less and less available.

"(5) The legislative history of the Controlled Substances Act makes clear that the Bureau is to schedule drugs based upon their potential for abuse, and 'should not be required to wait until a number of lives have been destroyed or substantial problems have arisen before designating a drug as subject to controls.'

Based upon this assessment the Director concluded that:

"control of all anorectic drugs is desirable at this time to insure that they will not become widely abused. This scheduling will fulfill the Congressional mandate to act before substantial problems have arisen."

22. No objections were received and phendimetrazine was placed in Schedule III pursuant to an order filed on June 12, 1975 (annexed hereto as Exhibit 8) in which the Director made the following findings required by 21 U.S.C. §812(b):

"1. Based on information now available phendimetrazine has a potential for abuse less than the drugs or other substances currently listed in Schedule II. Although chemically and pharmacologically this drug is closely related to the other anorectic drugs now being controlled and to the stimulants now listed in schedule II, present data regarding excessive usage, diversion, illicit sales, and abuse of phendimetrazine is not substantial enough to warrant a finding that it has a potential for abuse equal to the stimulants in schedule II.

"2. Phendimetrazine has a currently accepted medical use in treatment in the United States.

"3. Abuse of phendimetrazine may lead to high psychological dependence."

23. One objection to the proposed scheduling of phentermine was received. (The objection was filed by Pennwalt Corporation, a phentermine manufacturer.) Accordingly, on June 12, 1973, when the Director ordered that phendimetrazine, and other drugs being considered for scheduling, be placed in Section 812 schedules, his order did not include phentermine. Instead, preparations were begun for a hearing to be held pursuant to 21 U.S.C. § 811(a), on Pennwalt's objection to the Director's proposal to schedule phentermine. However, BNDD was concerned that phentermine could be a target for abuse while the hearing was being conducted. Therefore, the Director asked Pennwalt -- the only objector to placing phentermine in Schedule III -- whether Pennwalt would object to the Director placing phentermine in Schedule IV for the duration of the hearings. Pennwalt stated that it had no objection.

24. Since the pertinent regulatory controls in Schedules III and IV are substantially the same, and the legal procedures for placing drugs in the two schedules are identical, the Director construed 21 U.S.C. §811 to authorize the May 1, 1973, notice which proposed placing phentermine in Schedule III as the Notice of Proposed rulemaking for placing phentermine in Schedule IV. Since Pennwalt, the only objector to a Schedule III placement, consented to the Director's new proposal, there were no objections to placing phentermine in Schedule IV. Nonetheless, BNDD staff members consulted with manufacturers of phentermine's competitors, and determined that these manufacturers did not oppose placing phentermine in Schedule IV.

25. The Director made the following findings concerning phentermine in an order that he signed on July 6, 1973, (38 Fed. Reg. 18013; annexed hereto as Exhibit 9):

> "1. Based on information now available, phentermine has a low potential for abuse relative to the drugs or other substances currently listed in Schedule III.

"2. Phentermine has a currently accepted medical use in treatment in the United States.

"3. Abuse of phentermine may lead to limited psychological dependence relative to the drugs or other substances in Schedule III."

Accordingly, the Director announced in the Notice that he had placed phentermine in Schedule IV.

26. Pre-hearing conferences, discovery and motions on Pennwalt's objection to placing phentermine in Schedule III were conducted in late 1973 and early 1974.

27. I left the Chief Counsel's office early in 1974. On information and belief, Pennwalt and BNDD thereafter agreed during the course of pre-hearing proceedings, tha BNDD would not then press its proposal to place phentermine on Schedule III, but that phentermine would remain in Schedule IV as previously announced in the Director's order issued June 12, 1973, and along with the other newly, scheduled anorectic drugs, would be further evaluated 18 month after June 12, 1973. A review of the propriety of placing phentermine on Schedule IV was commenced in the spring of 1975, and is still continuing.

WILLIAM W. VODRA

Sworn to before me this
day of January, 1976

federal register

Area Code 202 Phone 962-8626

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Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER C—DRUGS

PART 130—NEW DRUGS

Amphetamines for Human Use

On August 6, 1970, there was published in the FEDERAL REGISTER (35 FR 12652) § 130.46 concerning amphetamines and their salts and levamfetamine and its salts. Section 130.46 required the submission of new drug applications for amphetamine or dextroamphetamine and their salts as a condition for continued marketing. The new drug applications were

[1] Attachment A filed as part of the original document.

to contain evidence of efficacy, including efficacy in the treatment of obesity.

Pursuant to that requirement 106 new drug applications for amphetamines or amphetamine-containing drugs were received. The analysis of the data submitted concerning the amphetamines and other, nonamphetamine anorectic drugs generally supported the efficacy of anorectic drugs. Use of the drug in obese patients was associated with more weight loss than was diet alone. The degree of extra weight loss was small (a few tenths of a pound a week in many cases), variations were great, and the rate of weight loss decreased after the first weeks of therapy.

On the basis of the currently available evidence the Commissioner concludes that oral dosage forms of amphetamine and/or dextroamphetamine are effective in the management of exogenous obesity as a short term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction for patients in whom obesity is refractory to other measures. Appropriate notices concerning such drugs which have been reviewed in the Drug Efficacy Study will be published in the FEDERAL REGISTER.

Use of amphetamines for long periods of time may lead to drug dependence and abuse. Abuse of the amphetamines has been well known. Persistence of abuse under conditions of marketing described herein may lead the Commissioner to take further steps to restrict the use of these drugs.

No data have been received providing substantial evidence of effectiveness of levamfetamine and its salts. Accordingly these preparations continue to be regarded as new drugs requiring approved full new drug applications.

On September 3, 1971, a Drug Efficacy Study Implementation notice was published in the FEDERAL REGISTER (36 FR 17069) stating that methamphetamine hydrochloride injection (intended for other than anorectic indications) was regarded as effective for some indications and less than effective for others. The Commissioner has now fully reviewed the evidence on the safety and effectiveness of this drug, and has concluded that the well-documented history of abuse of parenteral methamphetamine, together with the severe risk of dependence and the availability of safer and equally effective alternative drugs, creates an unfavorable balance of risk to benefit. A proposal to withdraw approval of those new drug applications as lacking evidence of safety is published elsewhere in this issue of the FEDERAL REGISTER. The Commissioner also concludes that, for the same reasons, parenteral preparations containing amphetamine, dextroamphetamine, or levamfetamine or their salts are lacking evidence of safety.

On August 8, 1970, a Drug Efficacy Study Implementation notice was published in the FEDERAL REGISTER (35 FR 12678) stating that various combination drugs containing an anorectic drug were regarded as possibly effective for their claimed anorectic effects and lacking substantial evidence of effectiveness for their other indications. Data were received concerning these drugs and also combination drugs which were subjects of new drug applications submitted as required by § 130.46. The combinations consisted of anorectic agents associated with, for example, sedatives, tranquilizers, rauwolfia derivatives, or vitamins. The data were reviewed and found not to fulfill the criteria set forth in the Statement of General Policy or Interpretation § 3.86 Fixed-combination prescription drugs for humans, published in the FEDERAL REGISTER of October 15, 1971 (36 FR 20037). Further, in view of the lack of substantial evidence of effectiveness of the drugs as fixed combinations, the recognized potential for abuse of the amphetamine, dextroamphetamine, methamphetamine, and phenmetrazine components and the availability of alternative therapeutic measures which are safer and effective, combinations containing such components also lack proof of safety. Proceedings to withdraw approval of such applications are being initiated, and an appropriate notice is published elsewhere in this issue of the FEDERAL REGISTER.

In a forthcoming issue of the FEDERAL REGISTER, the Commissioner will set forth his policy with respect to anorectic agents in general.

On the basis of all of the data and information submitted pursuant to § 130.46, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502 (f), (j), 505, 701(a), 52 Stat. 1051–53; as amended, 1055; 21 U.S.C. 352(f), (j), 355, 371(a)), and under the authority delegated to him (21 CFR 2.120), the Commissioner of Food and Drugs hereby revises § 130.46 of Part 130, Subpart A to read as follows:

§ 130.46 Amphetamines (amphetamine, dextroamphetamine, and their salts and levamfetamine and its salts) for human use.

(a) **Amphetamine and dextroamphetamine and their salts.** (1) Pursuant to the drug efficacy requirements of the Federal Food, Drug, and Cosmetic Act, the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, has evaluated certain dosage forms of amphetamines and other sympathomimetic stimulant drugs intended for use in the treatment of obesity and for other uses. The Academy found that such drugs as a class have been shown to have a generally short-term anorectic action. They further commented that clinical opinion on the contribution of the sympathomimetic stimulants in a weight reduction program varies widely, the anorectic effect of these drugs often plateaus or diminishes after a few weeks, most studies of them are for short periods, no available evidence shows that use of anorectic alters the natural history of obesity, some evidence indicates that anorectic effects may be strongly influenced by the suggestibility of the patient, and reservations exist about the adequacy of the

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controls in some of the clinical studies. Their significant potential for drug abuse was also cited.

(2) In addition to those dosage forms that were reviewed for efficacy by the Academy, other dosage forms of amphetamine drugs are on the market that were not cleared through the new-drug procedures. While certain amphetamines were marketed prior to enactment of the Federal Food, Drug, and Cosmetic Act in 1938, some of the conditions of use subsequently prescribed, recommended, or suggested in their labeling (for example, for the treatment of obesity) differ from uses claimed for the amphetamines before said enactment. Such uses have not been cleared through the effectiveness provisions of the Drug Amendments of 1962 (Public Law 87-781 which amended the Federal Food, Drug, and Cosmetic Act). These drugs are very extensively used in the treatment of obesity. The extent of use for such purposes as narcolepsy and minimal brain dysfunction in children is believed to be minor as compared with the total usage of these drugs. Because of their stimulant effect on the central nervous system, they have a potential for misuse by those to whom they are available through a physician's prescription, and their abuse by those who obtain them through illicit channels is well documented. Production data indicate that amphetamines have been produced and prescribed in quantities greatly in excess of demonstrated medical needs.

(3) Pursuant to a notice published in the FEDERAL REGISTER of August 8, 1970 (35 FR 12652), which required the submission of new drug applications as a condition for continued marketing of amphetamines, 106 new drug applications for amphetamines or amphetamine-containing drug products were received. The data submitted in those applications, and data obtained from other sources concerning anorectic drugs, generally supported the efficacy of anorectic drugs.

(b) On the basis of currently available evidence derived from short-term studies, the Commissioner concludes that single drug entity oral dosage forms of amphetamine or dextroamphetamine are effective in the management of exogenous obesity as a short-term (a few weeks) adjunct in a regimen of weight reduction, based on caloric restrictions, for patients in whom obesity is refractory to other measures. For purposes of this regulation, a mixture of dextroamphetamine and amphetamine is ordinarily regarded as a single drug entity.

(c) The Food and Drug Administration is not aware of data providing substantial evidence of the effectiveness of levamfetamine and its salts and regards these preparations as new drugs requiring approval full new-drug applications.

(d) In view of the well-documented history of abuse of parenteral amphetamines the severe risk of drug dependence, and the availability of safer alternative parenteral drugs which are equally effective for recognized non-anorectic indications, the Food and Drug Administration regards parenteral amphetamines as lacking evidence of safety.

(e) Any combination drug containing amphetamine or dextroamphetamine is regarded as a new drug requiring an approved full new-drug application as a condition for marketing. Data in new-drug applications are required to fulfill the criteria set forth in § 3.86 governing fixed combination prescription drugs for humans.

(f) New drug applications have been received from persons marketing orally administered single entity amphetamine or dextroamphetamine dosage forms. Any other person who intends to market such drug is required to submit to the Food and Drug Administration an abbreviated new drug application (§ 130.4 (f)) except that in addition, the application shall contain full information required under items 7 and 8 (composition and methods, facilities, and controls) of the new drug application form FD-356H (§130.4(c)).

(g) The labeling conditions for single entity oral dosage forms of amphetamine and dextroamphetamine and their salts are as follows:

(1) The label shall bear the statement "Caution: Federal law prohibits dispensing without prescription".

(2) The drug shall be labeled to comply with all requirements of the act and regulations. The labeling shall bear adequate information for safe and effective use of the drug. The indications for use are:

Narcolepsy.

Minimal brain dysfunction in children (hyperkinetic behavior disorders), as an aid to general management.

Management of exogenous obesity as short-term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction, for patients in whom obesity is refractory to other measures.

(3) Complete labeling guidelines are available from the Food and Drug Administration.

(h) Regulatory proceedings will be initiated with regard to any such drug within the jurisdiction of the act which is not in accord with this regulaton.

Effective date. This regulation shall be effective on March 14, 1973.

Dated: February 7, 1973.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.73-2717 Filed 2-9-73;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[DESI 5378; Docket No. FDC-D-582; NDA No. 9-946 etc.]

CERTAIN COMBINATION ANORECTIC DRUGS

Opportunity for Hearing on Proposal To Withdraw Approval of New Drug Applications

In notice (DESI 5378) published in the FEDERAL REGISTER of August 8, 1970 (35 FR 12673), the Commissioner of Food and Drugs announced his conclusions pursuant to the evaluation of a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the drugs described below stating that the drugs were regarded as possibly effective and lacking substantial evidence of effectiveness for the various labeled indications.

NDA No.	Drug	NDA Holder
9-946	Du-Oria tablets containing 10 milligrams methamphetamine hydrochloride, and 0.25 milligram reserpine per sustained release tablet.	Formerly marketed by B. F. [illegible]cher & Co., Inc., Post Office Box 847, Kansas City, MO 64130.
10-2[illegible]	Dexserpine "5" tablets containing 5 milligrams dextroamphetamine sulfate and 0.1 milligram reserpine per tablet.	Formerly marketed by Nysco Laboratories, Inc., 2[illegible] Vernon Boulevard, Long Island City, NY 11[illegible]
11-260	Bamadex tablets containing 5 milligrams dextroamphetamine sulfate and 400 milligrams meprobamate per tablet.	Lederle Laboratories Division, American Cyanamid Co., Post Office Box 871, Pearl River, NY 10[illegible]
11-522	Obetrol-10 and Obetrol-20 tablets, respectively, containing 2.5 milligrams each or 5 milligrams each of methamphetamine saccharate, methamphetamine hydrochloride, amphetamine sulfate, dextroamphetamine sulfate per tablet.	Obetrol Pharmaceuticals, Division of Rexar Pharmacal Corp., 3[illegible] Schenck Avenue Brooklyn, NY 11207.
11-538	Biphetamine-T "12½" capsules and Biphetamine-T "20" capsules, respectively, containing 6.25 milligrams each of dextroamphetamine and amphetamine, and 40 milligrams methaqualone per capsule, and 10 milligrams each of dextroamphetamine and amphetamine and 40 milligrams methaqualone per capsule, as resination exchange resin complexes of sulfonated polystyrene.	Strasenburgh Pharmaceutical, Division Penwalt Corp., 755 Jefferson Road, Rochester NY 14623.
12-042	Eskatrol spansules containing 15 milligrams dextroamphetamine sulfate and 7.5 milligrams prochlorperazine (as the maleate) per sustained release capsule.	Smith Kline & French Laboratories, 1500 Spring Garden Street, Philadelphia, PA 19101.
12-127	Appetrol tablets containing 5 milligrams dextroamphetamine sulfate and 400 milligrams meprobamate per tablet.	Wallace Pharmaceuticals, Division of Carter-Wallace, Inc., Half Acre Road, Cranbury, NJ 08512.
12-371	Prelu-Vite capsules containing 25 milligrams phenmetrazine hydrochloride, 2,000 USP units vitamin A, 200 USP units vitamin D, 2 milligrams thiamine mononitrate, 2 milligrams riboflavin, 20 milligrams niacinamide, 3 milligrams calcium pantothenate, 1 milligram pyridoxine hydrochloride, 0.5 microgram of vitamin [illegible] concentrate, 37.5 milligrams ascorbic acid, 5 milligrams iron, 140 milligrams calcium, 108 milligrams phosphorus, 0.1 milligram iodine and 1 milligram copper per capsule.	Formerly marketed by Geigy Pharmaceuticals, Division of CIBA-Geigy Co., Saw Mill River Road, Ardsley, N.Y. 10502.
12-415	Delfeta-sed Stedytabs containing [illegible] milligrams dl-methamphetamine hydrochloride [illegible] milligrams amobarbital per sustained-release [illegible]	Eastern Research Laboratories Inc., 302 South Central Avenue, Baltimore, MD 21202.
12-570	Bamadex Sequels containing 15 [illegible] grams dextroamphetamine sulfate and 300 milligrams meprobamate per sustained-release capsule.	Lederle Laboratories Division, American Cyanamid.
12-624	Obetrol-S.R. capsules containing 15 milligrams dextroamphetamine sulfate and 300 milligrams meprobamate per sustained-released capsule.	Wallace Pharmaceuticals.

Data submitted pursuant to the notice have been reviewed and found not to provide substantial evidence that the drugs are effective as fixed combinations for their claimed uses.

In view of the lack of substantial evidence of effectiveness of the drugs as fixed combinations, the recognized potential for abuse of the amphetamine, dextroamphetamine, methamphetamine, and phenmetrazine components, and the availability of alternative therapeutic measures which are safer and effective, the combination products are also regarded as lacking proof of safety. Data submitted in response to the notice of August 8, 1970, do not support a contention that the combination products decrease the incidence or severity of side effects associated with the single ingredient or that the additional component(s) lessens the abuse potential as compared to that of the single entity anorectic drug. Also, the known adverse effects associated with phenothiazine drugs raises an additional question of safety of use of Eskatrol which contains dextroamphetamine sulfate in combination with prochlorperazine.

With further respect to Eskatrol, the Food and Drug Administration is aware of a study conducted by Dr. Carl Chambers relating to the abuse potential of the product, and for which no report has been submitted by the NDA holder pursuant to section 505(j) of the act and §§ 130.13 and 130.35 of the regulations (21 CFR 130.13 and 130.35).

Therefore, notice is given to the holder(s) of the new drug application(s) and to any other interested person that the Commissioner proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval of the listed new drug application(s) and all amendments and supplements thereto on the grounds that new information before him with respect to the drug(s), evaluated together with the evidence available to him at the time of approval of the application(s), shows that: (1) There is a lack of substantial evidence that the drug(s) will have all the effects they purport or are represented to have; and (2) the drugs are not shown to be safe for use under the conditions of use prescribed, recommended, or suggested in the labeling; and (3) further, in the case of Eskatrol tablets, the applicant has deliberately failed to make required reports in accordance with section 505(j) of the act (21 U.S.C. 355(j)) and § 130.13 and § 130.35 of the new drug regulations (21 CFR 130.13 and 130.35).

All identical, related, or similar products, not the subject of an approved new drug application, are covered by the new drug application(s) reviewed. See 21 CFR 130.40 (37 FR 23183, October 31, 1972). Any manufacturer or distributor of such an identical, related, or similar product is an interested person who may in response to this notice submit data and information, request that the new drug application(s) not be withdrawn, request a hearing, and participate as a party in any hearing. Any person who wishes to determine whether a specific product is covered by this notice should write to the

Food and Drug Administration, Bureau of Drugs, Office of Compliance (BD-300), 5600 Fishers Lane, Rockville, MD 20852.

In accordance with the provisions of section 505 of the act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Part 130), the Commissioner hereby gives the applicant(s) and any other interested person an opportunity for a hearing to show why approval of the new drug application(s) should not be withdrawn.

The applicant(s) and any other interested person is required to file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852, on or before March 14, 1973, a written appearance electing whether or not to avail himself of the opportunity for a hearing. Failure of an applicant or any other interested person to file a written appearance of election by March 14, 1973, will constitute an election by him not to avail himself of the opportunity for a hearing.

If no person elects to avail himself of the opportunity for a hearing, the Commissioner without further notice will enter a final order withdrawing approval of the application(s).

If an applicant or any other interested person elects to avail himself of the opportunity for a hearing, he must file, on or before March 14, 1973, a written appearance requesting the hearing, giving the reasons why approval of the new drug application(s) should not be withdrawn, together with a well-organized and full-factual analysis of the clinical and other investigational data he is prepared to prove in support of his opposition. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that a genuine and substantial issue of fact requires a hearing (21 CFR 130.14(b)).

If review of the data submitted by an applicant or any other interested person warrants the conclusion that there exists substantial evidence demonstrating the effectiveness of the product(s) and evidence that the drug(s) is (are) safe for use for the labeling claims involved (and, in the case of NDA 12-042, that there has been no violation of section 505(j) of the act), the Commissioner will rescind this notice of opportunity for hearing.

If review of the data in the application(s) and data submitted by the applicant(s) or any other interested person in a request for a hearing, together with the reasoning and factual analysis in a request for a hearing, warrants the conclusion that no genuine and substantial issue of fact precludes the withdrawal of approval of the application(s), the Commissioner will enter an order of withdrawal making findings and conclusions on such data.

If, upon the request of the new drug applicant(s) or any other interested person, a hearing is justified, the issues will be defined, a hearing examiner will be named, and he shall issue, as soon as practicable after March 14, 1973, a written notice of the time and place at which the hearing will commence. All persons interested in identical, related, or similar products covered by the new drug application(s) will be afforded an opportunity to appear at the hearing, file briefs, present evidence, cross-examine witnesses, submit suggested findings of fact, and otherwise participate as a party. The hearing contemplated by this notice will be open to the public except that any portion of the hearing that concerns a method or process the Commissioner finds entitled to protection as a trade secret will not be open to the public, unless the respondent specifies otherwise in his appearance.

Requests for a hearing and/or elections not to request a hearing may be seen in the Office of the Hearing Clerk (address given above) during regular business hours, Monday through Friday.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-53, as amended; 21 U.S.C. 355), and the Administrative Procedure Act (5 U.S.C. 554), and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: February 7, 1973.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.73-2716 Filed 2-9-73;8:45 am]

[DESI 11673]

CERTAIN ORAL ANORECTIC PREPARATIONS: PHENTERMINE HYDROCHLORIDE; PHENDIMETRAZINE TARTRATE; BENZPHETAMINE HYDROCHLORIDE; DIETHYLPROPION HYDROCHLORIDE

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following anorectic drugs:

1. Wilpo tablets, containing 8 mg. phentermine hydrochloride per tablet; Dorsey Laboratories, Division of Sandoz-Wander Inc., Northeast, U.S. 6 and Interstate 80, Lincoln, Nebr. 68501 (NDA 12-737).

2. Didrex tablets, containing 25 mg. and 50 mg. benzphetamine hydrochloride per tablet; The Upjohn Co., 7171 Portage Road, Kalamazoo, MI 49001 (NDA 12-427).

3. Plegine tablets, containing 35 mg. phendimetrazine tartrate per tablet; Ayerst Laboratories, Rouses Point, N.Y. 12979 (NDA 12-248).

4. Tepanil tablets, containing 25 mg. diethylpropion hydrochloride per tablet; The Merrell-National Drug Co., Division of Richardson-Merrell, Inc., 110 East Amity Road, Cincinnati, OH 45215 (NDA 11-673).

5. Tenuate tablets, containing 25 mg. diethylpropion hydrochloride per tablet; The Merrell-National Drug Co., Division of Richardson-Merrell, Inc. (NDA 11-722).

6. Preludin Endurets (prolonged-action tablets), containing phenmetrazine hydrochloride: Geigy Pharmaceuticals, Division of Ciba-Geigy Corp., Ardsley, N.Y. 10502 (NDA 11-752).

Although not specifically referred to the Academy for review, Preludin tablets, a conventional oral dosage form containing phenmetrazine hydrochloride (NDA 10-460, Geigy Pharmaceuticals) was approved on the basis of safety prior to 1962, was evaluated by the Academy, and is appropriately included herein.

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). Supplemental new drug applications are required to revise the labeling in and to update previously approved applications providing for such drugs. A new drug application is required from any person marketing such drug without approval.

I. SUSTAINED-ACTION, TIMED-RELEASE, OR OTHER DELAYED OR PROLONGED-EFFECT FORMS OF PHENMETRAZINE HYDROCHLORIDE

The Food and Drug Administration has considered the Academy's report, as well as other available evidence, and concludes that phenmetrazine hydrochloride in prolonged-action tablet form is less than effective (possibly effective) with respect to any special claim for prolonged action when offered for the management of exogenous obesity as a short-term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction.

Any data submitted in response to this notice to support claims for which the drug is classified as other than effective must be previously unsubmitted and include data from adequate and well-controlled clinical investigations (identified for ready review) as described in § 130.12 (a)(5) of the regulations published in the FEDERAL REGISTER of May 8, 1970 (35 FR 7250). Carefully conducted and documented clinical studies obtained under uncontrolled or partially controlled situations are not acceptable as a sole basis for approval of claims of effectiveness, but such studies may be considered on their merits for corroborative support of efficacy and evidence of safety.

II. CONVENTIONAL TABLET FORMS OF PHENMETRAZINE HYDROCHLORIDE; PHENTERMINE HYDROCHLORIDE; BENZPHETAMINE HYDROCHLORIDE; PHENDIMETRAZINE TARTRATE; OR DIETHYLPROPION HYDROCHLORIDE

A. *Effectiveness classification.* The Food and Drug Administration has considered the Academy's reports, as well as other available evidence, and concludes that these drugs, administered in conventional oral dosage form, are effective in the management of exogenous obesity as a short-term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction.

B. *Conditions for approval and marketing.* The Food and Drug Administration is prepared to approve abbreviated new drug applications and abbreviated supplements to previously approved new drug applications under conditions described herein.

1. *Form of drug.* Such preparations are in tablet dosage form suitable for oral administration.

2. *Labeling conditions.* The label bears the statement, "Caution: Federal law prohibits dispensing without prescription."

The drugs are labeled to comply with all requirements of the Act and regulations, and the labeling bears adequate information for safe and effective use of the drug(s). The "Indications" section is as follows:

INDICATIONS

(*Name of drug*) is indicated in the management of exogenous obesity as a short term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction. The limited usefulness of agents of this class (see ACTIONS) should be measured against possible risk factors inherent in their use such as those described below.

In addition, the labeling contains the following "Actions" section and drug dependence warning the "Warnings" section:

ACTIONS

(*Name of drug*) is a sympathomimetic amine with pharmacologic activity similar to the prototype drugs of this class used in obesity, the amphetamines. Actions include central nervous system stimulation and elevation of blood pressure. Tachyphylaxis and tolerance have been demonstrated with all drugs of this class in which these phenomena have been looked for.

Drugs of this class used in obesity are commonly known as "anorectics" or "anorexigenics". [illegible] not been established, however, that the action of such drugs in treating obesity is primarily one of appetite suppression. Other central nervous system actions, or metabolic effects, may be involved, for example.

Adult obese subjects instructed in dietary management and treated with "anorectic" drugs, lose more weight on the average than those treated with placebo and diet, as determined in relatively short-term clinical trials.

The magnitude of increased weight loss of drug-treated patients over placebo-treated patients is only a fraction of a pound a week. The rate of weight loss is greatest in the first weeks of therapy for both drug and placebo subjects and tends to decrease in succeeding weeks. The possible origins of the increased weight loss due to the various drug effects are not established. The amount of weight loss associated with the use of an "anorectic" drug varies from trial to trial, and the increased weight loss appears to be related in part to variables other than the drug prescribed, such as the physician-investigator, the population treated, and the diet prescribed. Studies do not permit conclusions as to the relative importance of the drug and non-drug factors on weight loss.

The natural history of obesity is measured in years, whereas the studies cited are restricted to a few weeeks duration; thus, the total impact of drug-induced weight loss over that of diet alone must be considered clinically limited.

WARNINGS

DRUG DEPENDENCE: (*Name of drug*) is related chemically and pharmacologically to the amphetamines. Amphetamines and related stimulant drugs have been extensively abused, and the possibility of abuse of (*name of drug*) should be kept in mind when evaluating the desirability of including a drug as part of a weight reduction program. Abuse of amphetamines and related drugs may be associated with intense psychological dependence and severe social dysfunction. There are reports of patients who have increased the dosage to many times that recommended. Abrupt cessation following prolonged high dosage administration results in extreme fatigue and mental depression; changes are also noted on the sleep EEG. Manifestations of chronic intoxication with anorectic drugs include severe dermatoses, marked insomnia, irritability, hyperactivity, and personality changes. The most severe manifestation of chronic intoxications is psychosis, often clinically indistinguishable from schizophrenia.

3. *Marketing status.* Marketing of such drugs may be continued under the conditions described in the notice entitled Conditions for Marketing New Drugs Evaluated in Drug Efficacy Study, published in the FEDERAL REGISTER July 14, 1970 (35 FR 11273), as follows:

a. For holders of "deemed approved" new drug applications (i.e., an application which became effective on the basis of safety prior to October 10, 1962), the submission of a supplement for revised labeling and a supplement for updating information, including full manufacturing information with respect to items 7 and 8 of Form FD-356H (§ 130.4(c)), as described in paragraph (a)(1)(i) and (iii) of the notice of July 14, 1970.

b. For any person who does not hold an approved or effective new drug application, the submission of an abbreviated new drug application as described in paragraph (a)(3)(i) of that notice, except that full manufacturing information with respect to items 7 and 8 of Form FD-356H (§ 130.4(c)) is required.

c. For any distributor of the drug, the use of labeling in accord with this announcement for any such drug shipped within the jurisdiction of the Act as described in paragraph (b) of that notice.

Each of the above-named holders of the new drug applications for these drugs has been mailed a copy of the Academy's report. Communications forwarded in response to this announcement should be identified with the reference number DESI 11673, directed to the attention of the following appropriate office, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852:

Supplements (identify with NDA number): Office of Scientific Evaluation (BD-100), Bureau of Drugs.

Original abbreviated new drug applications (identify as such): Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.

Requests for the Academy's report: Drug Efficacy Study Implementation Information Control (BD-60), Bureau of Drugs.

All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.

All identical, related, or similar products, not the subject of an approved new drug application, are covered by the new drug applications reviewed and are subject to this notice. See 21 CFR 130.40 (37 FR 23185, October 31, 1972). Any person who wishes to determine whether a specific product is covered by this notice should write to the Food and Drug Administration, Bureau of Drugs, Office of Compliance (BD-100), 5600 Fishers Lane, Rockville, MD 20852.

This notice is issued pursuant to the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-53, as amended; 21 U.S.C. 352, 355) and the Administrative Procedure Act (5 U.S.C. 554), and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: February 7, 1973.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.73-2716 Filed 2-9-73;8:45 am]

[DESI 12101]

COMBINATION DRUG CONTAINING SYROSINGOPINE AND HYDROCHLOROTHIAZIDE

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group on the following drug:

Singoserp-Esidrix Tablets (2 strengths) containing syrosingopine and hydrochlorothiazide; Ciba Pharmaceutical Company, Division of Ciba-Geigy Corp., 556 Morris Avenue, Summit, NJ 07901 (NDA 12-101).

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). The effectiveness classification is described below.

A. *Effectiveness classification.* The Food and Drug Administration has considered the Academy's reports, as well as other available evidence, and concludes that the drug is less than effective (possibly effective) for its labeled indications.

B. *Submission of data.* Any data submitted in response to this notice to support indications for which the drug is classified as less than effective must be previously unsubmitted and include data from adequate and well-controlled clinical investigations (identified for ready review) as described in § 130.12 (a)(5) of the regulations published in the FEDERAL REGISTER of May 8, 1970 (35 FR 7250). Carefully conducted and documented clinical studies obtained under uncontrolled or partially controlled situations are not acceptable as a sole basis for approval of claims of effectiveness, but such studies may be considered on their merits for corroborative support of efficacy and evidence of safety.

A copy of the Academy's report has been furnished to the firm referred to above. Communications forwarded in response to this announcement should be identified with the reference number DESI 12101, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.

Supplements (identify with NDA number): Office of Scientific Evaluation (BD-100), Bureau of Drugs.

Requests for the Academy's report: Drug Efficacy Study Information Control (BD-66), Bureau of Drugs.

All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.

All identical, related, or similar products, not the subject of an approved new drug application, are covered by the new drug application(s) reviewed and are subject to this notice. See 21 CFR 130.40 (37 FR 23185, October 31, 1972). Any person who wishes to determine whether a specific product is covered by this notice should write to the Food and Drug Administration, Bureau of Drugs, Office of Compliance (BD-300), 5600 Fishers Lane, Rockville, MD 20852.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-53, as amended; 21 U.S.C. 352, 355) and the Administrative Procedure Act (5 U.S.C. 554) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: February 7, 1973.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.73-2714 Filed 2-9-73;8:45 am]

[DESI 5504; Docket No. FDC-D-587; NDAs 5-674; 5-757]

METHAMPHETAMINE HYDROCHLORIDE (PARENTERAL)

Opportunity for Hearing on Proposal To Withdraw Approval of New Drug Applications

The Food and Drug Administration published a notice (DESI 5504) in the FEDERAL REGISTER of February 23, 1971 (36 FR 3387), regarding the efficacy of the following drugs containing methamphetamine hydrochloride for parenteral use and classifying them as effective, probably effective, or lacking substantial evidence of effectiveness for certain indications.

NDA 5-674 (incorrectly listed as 5-504); Methedrine Injection; formerly marketed by Burroughs Wellcome & Co., Inc., 3030 Cornwallis Road, Research Triangle Park, NC 27709.

NDA 5-757; Drinalfa Injection; E. R. Squibb & Sons Georges Road, New Brunswick, N.J. 08903.

Subsequent to that notice, a publication in the FEDERAL REGISTER of August 8, 1972 (37 F.R. 15946), further ruled on those indications that had initially been classified as probably effective.

The Food and Drug Administration has recently reviewed the entire class of drugs offered for use as anorectic agents and the available evidence pertaining to their safe and effective use, including their potential for misuse and abuse. On the basis of this recent survey, the Commissioner of Food and Drugs concludes that the well-documented history of abuse of parenteral methamphetamine, together with the severe risk of dependence and the presence of effective alternative drugs, creates an unfavorable balance of risk to benefit.

Therefore, notice is hereby given to the holders of the new drug applications listed above and to any interested person who may be adversely affected, that the Commissioner of Food and Drugs proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval of the above new drug applications and all amendments and supplements thereto. It is proposed to withdraw approval of these applications on the grounds that new evidence, not contained in the new drug applications or not available to the Commissioner until after the applications were approved, evaluated together with the evidence available to him when the applications were approved, show that methamphetamine hydrochloride for parenteral administration is not shown to be safe for use under the conditions of use upon the basis of which the application was approved.

All identical, related, or similar products, not the subject of an approved new drug applications, are covered by the new drug applications reviewed. See 21 CFR 130.40 (37 FR 23185, October 31, 1972). Any manufacturer or distributor of such an identical, related or similar product is an interested person who may in response to this notice submit data and information, request that the new drug applications not be withdrawn, request a hearing, and participate as a party in any hearing. Any person who wishes to determine whether a specific product is covered by this notice should write to the Food and Drug Administration, Bureau of Drugs, Office of Compliance (BD-300), 5600 Fishers Lane, Rockville, MD 20852.

In accordance with the provisions of section 505 of the Act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Part 130), the Commissioner hereby gives the applicant(s) and any other interested person an opportunity for a hearing to show why approval of the new drug application(s) should not be withdrawn.

The applicant(s) and any other interested person is required to file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852, on or before March 14, 1973, a written appearance electing whether or not to avail himself of the opportunity for a hearing. Failure of an applicant or any other interested person to file a written appearance of election before March 14, 1973, will constitute an election by him not to avail himself of the opportunity for a hearing.

If no person elects to avail himself of the opportunity for a hearing, the Commissioner without further notice will enter a final order withdrawing approval of the application(s).

If an applicant or any other interested person elects to avail himself of the opportunity for a hearing, he must file, on or before March 14, 1973, a written appearance requesting the hearing, giving the reasons why approval of the new drug application(s) should not be withdrawn, together with a well-organized and full-factual analysis of the clinical and other investigational data he is prepared to prove in support of his opposition. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that a genuine and substantial issue of fact requires a hearing (21 CFR 130.14(b)).

If review of the data submitted by the applicant or any other interested person warrants the conclusion that the drug is safe for use under the conditions of use prescribed, recommended, or suggested in its labeling, the Commissioner will rescind this notice of opportunity for hearing.

If review of the data in the application(s) and data submitted by the applicant(s) or any other interested person in a request for a hearing, together with the reasoning and factual analysis in a request for a hearing, warrants the conclusion that no genuine and substantial issue of fact precludes the withdrawal of approval of the application(s), the Commissioner will enter an order of withdrawal making findings and conclusions on such data.

If, upon the request of the new drug applicant(s) or any other interested person, a hearing is justified, the issues will be defined, a hearing examiner will be named, and he shall issue, as soon as practicable after March 14, 1973, a written notice of the time and place at which the hearing will commence. All persons interested in identical, related, or similar products covered by the new drug application(s) will be afforded an opportunity to appear at the hearing, file briefs, present evidence, cross-examine witnesses, submit suggested findings of fact, and otherwise participate as a party. The hearing contemplated by this notice will be open to the public except that any portion of the hearing that concerns a method or process the Commissioner finds entitled to protection as a trade secret will not be open to the public, unless the respondent specifies otherwise in his appearance.

Requests for a hearing and/or elections not to request a hearing may be seen in the Office of the Hearing Clerk (address given above) during regular business hours, Monday through Friday.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-53, as amended; 21 U.S.C. 355), and the Administrative Procedure Act (5 U.S.C. 554), and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: February 7, 1973.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.73-2715 Filed 2-9-73;8:45 am]

BEST COPY AVAILABLE

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

156a

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FEB 15 1973

John E. Ingersoll
Director
Bureau of Narcotics and
Dangerous Drugs
Department of Justice
1405 Eye Street, N.W.
Washington, D.C. 20537

Dear Mr. Ingersoll:

The Food and Drug Administration has recently completed a review of all drugs currently marketed or proposed for marketing in the United States for the treatment of obesity. The marketed drugs include three substances already controlled under Schedule II of the Controlled Substances Act, amphetamine, methamphetamine, and phenmetrazine. The review also included drugs currently not controlled under any schedule, the marketed drugs, diethylpropion, benzphetamine, phendimetrazine, phentermine, and chlorphentermine, and the investigational substances, clortermine, mazindole, and fenfluramine. New drug applications have been submitted to the Food and Drug Administration for the latter three drugs, and approval is pending.

Review of data reveals that these drugs produce approximately the same degree of therapeutic effects in man as currently scheduled anorectics, as adjuncts in weight reduction in the obese. The review indicated that the drugs are also comparable in other ways to scheduled anorectics:

a. They are all closely related chemically, with the exception of mazindole.

b. Their pharmacological profiles are closely similar, except for certain aspects of the profile of fenfluramine.

c. Documentation of actual abuse or production of dependence in humans is irregular, but does exist for certain of the unscheduled anorectics. The skimpy documentation of abuse of these drugs appears due to the fortuitous nature of reports as currently obtained and to the past easy availability of cheaper and more potent stimulants, rather than to intrinsic lack of abuse potential.

d. We note the conclusions and recommendations of the WHO Expert Committee on Drug Dependence that these drugs either be subject to control or by analogy are similar to drugs recommended for control.

e. Certain specialized testing of fenfluramine suggests that the abuse potential of fenfluramine is of a lower order of magnitude than that of the other drugs under consideration.

We therefore conclude that all the above named drugs possess abuse potential and potential for producing drug dependence, and are so informing you as required under the provisions of Section 201(f) of the Controlled Substances Act. As provided for by Section 201(a), we further request that the Attorney General issue rules adding the above drugs to the schedules of the Controlled Substances Act, and recommend that the schedule for all drugs but fenfluramine be Schedule III, fenfluramine appearing more appropriately controlled under the provisions of Schedule IV.

We attach review material assembled by reviewing pharmacologists within the Food and Drug Administration for its possible utility to you, and as a basis for further discussion after your scientists have reviewed our recommendations and request.

Sincerely yours,

R. L. Seggel

Richard L. Seggel
Acting Assistant Secretary for Health

Attachment

Summary of circumstances associated with acquistion of drug

PHENDIMETRAZINE

J-1-71-0029 (5/27/71) -- In this case, a practicing pharmacist was distributing diverted pharmaceutical drugs to the southeastern Louisiana area. The defendant was arrested as he was enroute to deliver some drugs to BNDD agents. A search warrant was executed at his residence. Of the 3200 dosage units seized, 75 were phendimetrazine tablets.

G-1-72-0073 (5/14/72) -- Defendant was a physician who was illegally selling and dispensing amphetamines and barbiturates without medical examination on doctor-patient relationship. In May of 1972, 785 tablets of phendimetrazine were seized after arresting the defendant.

J-1-72-D541 (11/06/72) -- An agent was introduced to a pharmacist who wanted to sell Desoxyn, Biphetamine and Didrex. In the course of the investigations 1090 tablets and capsules of proprietary preparations of amphetamine and methamphetamine were purchased or seized as were 100 Ritalin and Didrex tablets, 200 Ionamin capsules, 300 phendimetrazine containing tablets or capsules, 6.9 grams of cocaine; 402 tablets or capsules of amphetamine - barbiturate proprietary combinations, 829 proprietary barbiturate containing tablets or capsules, 213 Valium and 194 Quaalude tablets, 400 codeine containing tablets and 23 grams of morphine sulfate. 100 tablets of a diuretic were among the drugs purchased.

Laboratory #2586 and #2587 -- Two (2) laboratory cases were samples received in November 1972 from the Hialeah Crime Laboratory in Miami, Florida. The samples were purchased by a detective and consisted of eleven and fifteen tablets which were identified as phendimetrazine.

I-1-73-0071 (2/20/73) -- A cooperating individual was able to purchase 390 tablets which were alleged to be amphetamine. Upon chemical analysis, the drug was determined as phendimetrazine. On February 23rd, the informant could buy 100,000 "black capsules" but he would have to purchase at least 10,000 of 30,000 phendimetrazine tablets they had.

Summary of Letters Documenting Phendimetrazine Abuse

PHENDIMETRAZINE

December 1972

"Phendimetrazine has been found in the New Jersey State Police Laboratory. Recently a thousand light green tablets were seized." The drug was identified by Infrared and Mass Spectroscopy.

January 1973

Three samples have been identified as phendimetrazine in the Pennsylvania State Police Crime Laboratory at Harrisburg. Ultraviolet and Infrared Spectra, thin layer chromatography, and chemical color tests were utilized to identify phendimetrazine. Upon receiving further samples, the identity of the excipients resembled the 35 mg "Bacarate" brand of phendimetrazine tartrate distributed by S.J. Tutag and Company, Detroit, Michigan.

February 1973

Ballistic examination by SCIL was completed on capsules submitted by the Mississippi Bureau of Narcotics. The capsules contained phendimetrazine tartrate but could not be identified as to manufacturing source.

February 1973

Mississippi Crime Laboratory were having a problem with an exhibit. The capsules, resembling Dexedrine, were bought by narcotic agents who were told they were amphetamines. Chemical tests were giving results which were dissimilar to those of amphetamine or any other drug they were familiar with. Examination by the Special Testing and Research Laboratory resulted in the findings that the capsules contained phendimetrazine tartrate but could not be identified as to manufacturing source.

February 1973

Phendimetrazine has also been reported by the Philadelphia Police Chemistry Laboratory. In one seizure ten (10) capsules were found to contain the drug. They were the same size as the standard amphetamine sulfate capsules but unimprinted, conventionally shaped and contained orange and white pellets.

Summary of Letters Documenting Phendimetrazine Abuse (continued)

PHENDIMETRAZINE

March 8, 1973

Within the past 30 days, the Northern Illinois Police Crime Laboratory has received a quantity of phendimetrazine as double scored pink tablets and double scored white tablets. Exhibits have also been processed which were in powder form.

March 8, 1973

The Drug Analysis Laboratory of the Pharmacology Department of the University of Louisville School of Medicine has frequently identified phendimetrazine tablets confiscated in this area. The tablets were not Ayerst Plegine but are plain white, well made tablets.

March 20, 1973

A letter was received from the Washington State Board of Pharmacy recommending the control of phendimetrazine under the Controlled Substances Act. In a recent case, over a million dosage units of this drug were confiscated. Further information indicated that the same practitioner has 1.4 million dosage units in storage, awaiting the outcome of the first case. The practitioners feel that this drug will give the same anorexic effects as amphetamines or amphetamine-like drugs.

Form DJ-156
(Ed. 4-26-63)

UNITED STATES GOVERNMENT

Memorandum

DEPARTMENT OF JUSTICE

161a

TO : Mr. Kenneth A. Durrin
Assistant Director for Compliance
Mr. Ernest A. Carabillo, Jr.
Chief, Drug Control Division

DATE: FEB 6 1973

FROM : Chief
Laboratory Division

SUBJECT: Phendimetrazine Tartrate

In a memorandum on this subject, September 1971, the Office of Scientific Support (SCI) alerted the Regional Offices and Laboratories that phendimetrazine would be a likely candidate for use by "fat doctors" as the result of re-scheduling amphetamines, methamphetamines, among others, and FDA rulings on use of some of these compounds in the treatment of obesity.

Although the occurrences have apparently been too few to justify positive conclusions, information in Laboratory Division (SCIL) indicates that there may be increased use of the compound. Below are instances that have come to our attention.

Analyses in BNDD laboratories (using phenmetrazine as a comparison):

Phenmetrazine	FY 72	FY 73 (Thru 12/31)
BNDD Submissions	17	7
Other Agency Submissions	19	32
TOTAL	36	39

Phendimetrazine	FY 72	FY 73 (Thru 12/31)
BNDD Submissions	0	0
Other Agency Submissions	2	5
TOTAL	2	5

Copies of the computer entry on each of the phendimetrazine analysis in FY 73 (thru 12/31/72) is attached.

Recently, several samples were submitted by the Texas State Diversion Investigation Unit to the Special Testing and Research Laboratory (SCILR) for ballistics. As a result, the following occurrences of phendimetrazine were identified:

8A-72-0058, Exh. 2, L-115895, 11-22-72, Lawrence A. Weisman, (S-4261): Phendimetrazine tartrate tablets. The manufacturer is unknown, but SCILR believes that there were probably made for distribution by S.J. Tutag and Company, Detroit, Michigan.

8A-72-0054, Exh. 1, L-115100, 9-18-72, Aubrey L. Lewis, M.D., (S-4245): Phendimetrazine tablets. Manufacturer is unknown.

8A-72-0054, Exh. 1, L-115415, 10-13-72, Aubrey L. Lewis, M.D. and Dorothy Davis, (S-4250): Phendimetrazine tablets. Manufacturer is unknown.

8A-72-0054, Exh. 1, L-115548, 10-21-72, Aubrey L. Lewis, M.D., (S-4287): Phendimetrazine tablets.

8A-72-0054, Exh. 2, L-115548, 10-21-72, Aubrey L. Lewis, M.D., (S-4288): Phendimetrazine tablets.

All of the tablets in the exhibits of 8A-72-0054, except for minor variations in dimension and in filled weights, were the same. The manufacturer is unknown.

From Laboratory Division, Pennsylvania State Police, Harrisburg, Pennsylvania, SCILR Lab Nos: S-4324, S-4325, and S-4326. Phendimetrazine tablets in first two exhibits and capsules in latter exhibit. Lack of authentic samples prevented identification of the manufacturer.

Finally, one additional encounter is known, although details are lacking, in an analysis by the New Jersey State Police Laboratory. (To be inserted in Microgram, Vol. VI, No. 1.)

Although phendimetrazine is not a controlled substance, Office of Compliance (ENA) may wish to obtain authentic sample for SCILR.

John W. Gunn, Jr.

cc: CC
DMD
All Chief Chemists

DRUG FOUND 1620 PHENDIMETRAZINE TARTRATE

WEEKLY
AS UA

LAB NO	A5840	REGIONAL LAB	WASHINGTON, D.C.
MND FILE		SUSPECTED DRUG	1620 PHENDIMETRAZINE TA
EXHIBIT	001A	AMT. REC	0001.00 TABLET
DATE REC	01/05/73	POTENCY	0000.0
HOURS	02.0	BALLISTICS	NO
WEEK ENDING	01/13/73		
DILUENT			

LAB NO	A5846	REGIONAL LAB	WASHINGTON, D.C.
MND FILE		SUSPECTED DRUG	1620 PHENDIMETRAZINE TA
EXHIBIT	0018	AMT. REC	0001.00 PARAPHN
DATE REC	01/05/73	POTENCY	0000.0
HOURS	01.5	BALLISTICS	NO
WEEK ENDING	01/13/73		
DESCR. DATA			

6 16a

LABORATORY ANALYSIS BY DRUGS
12/31/72

PROCESSING DATE 01/18/73

RTRATE

LOC. COLLECTED
STATE/COUNTRY DC WASHINGTON D.C.
BNDD REGION
OTHER AGENCY 1 LOCAL
TYPE AGENCY 1 LAW ENFORCEMENT

SUSPECTED FIRM 028 GEIGY

RTRATE

LOC. COLLECTED
STATE/COUNTRY DC WASHINGTON D.C.
BNDD REGION
OTHER AGENCY 1 LOCAL
TYPE AGENCY 1 LAW ENFORCEMENT

1-30 BOOTLE CAP

DRUG FOUND 1620 PHENDIMETRAZINE TARTRATE

LAB NO	2586	REGIONAL LAB	MIAMI
BNI FILE		SUSPECTED DRUG	1620 PHENMETRAZIN
EXHIBIT	1	AMT. REC	0011.00 TAB
DATE REC	11/30/72	POTENCY	0000.0
HOURS	02.0	BALLISTICS	NO
WEEK ENDING	12/09/72		

LAB NO	2587	REGIONAL LAB	MIAMI
BNI FILE		SUSPECTED DRUG	1620 PHENMETRAZIN
EXHIBIT	2	AMT. REC	0015.00 TAB
DATE REC	11/30/72	POTENCY	0000.0
HOURS	02.0	BALLISTICS	NO
WEEK ENDING	12/09/72		

164a

WEEKLY LABORATORY ANALYSIS BY DRUGS
AS OF 11/30/72

PAGE
PROCESSING DATE 12/15/7

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LOC. COLLECTED MIAMI
STATE/COUNTRY FLORIDA
BNDD REGION
OTHER AGENCY 1 LOCAL
TYPE AGENCY 1 LAW ENFORCEMENT

E HCL
LET

LOC. COLLECTED MIAMI
STATE/COUNTRY FLORIDA
BNDD REGION
OTHER AGENCY 1 LOCAL
TYPE AGENCY 1 LAW ENFORCEMENT

WEEKLY LABORATORY ANALYSIS BY DRUGS
AS OF 12/27/72

PROCESSING DATE 12/29/72

DRUG FOUND 1620 PROMETHAZINE TARTRATE

LAB NO	25134	REGIONAL LAB	WASHINGTON, D.C.		LOC. COLLECTED	ANDREWS AFB
BND FILE		SUSPECTED DRUG	NONE		STATE/COUNTRY	MD MARYLAND
EXHIBIT	005A	AMT. REC	0020.00	TABLET	BNDD REGION	
DATE REC	12/27/72	POTENCY	0000.0		OTHER AGENCY	3 FEDERAL
HOURS	02.0	BALLISTICS	NO		TYPE AGENCY	1 LAW ENFORCEMENT
WEEK ENDING	12/16/72				SUSPECTED FIRM	124 TUTAG
QUENT						

185

PAGE 1

WLER... LABORATORY ANALYSIS BY DRUGS
AS OF 12/07/72

PROCESSING DATE 12/29/72

DRUG FOUND 1o20 PHENDIMETRAZINE TARTRATE

LAB NO	25134	REGIONAL LAB	WASHINGTON, D.C.		
3ND FILE		SUSPECTED DRUG	NONE		
EXHIBIT	005A	ART. REC	0020.00	TABLET	
DATE REC	10/27/72	POTENCY	0000.0		
HOURS	72.0	BALLISTICS	NO		
WEEK ENDING	12/16/72				
COUNT					

LOC. COLLECTED ANDREWS AFB
STATE/COUNTRY MD MARYLAND
UNOD REGION
OTHER AGENCY 3 FEDERAL
TYPE AGENCY 1 LAW ENFORCEMENT

SUSPECTED FIRM 124 TUTAG

A 166a

DRUG FOUND 1620 PHENDIMETRAZINE TARTRATE

WEEKLY LABORATORY ANALYSIS BY DRUGS
AS OF 12/31/72

PROCESSING DATE 01/18/73

LAB NO	A5840	REGIONAL LAB	WASHINGTON, D.C.	LOC. COLLECTED STATE/COUNTRY	DC WASHINGTON D.C.
BNDD FILE		SUSPECTED DRUG	1620 PHENDIMETRAZINE TARTRATE	BNDD REGION	
EXHIBIT	001A	AMT. REC	0001.00 TABLET	OTHER AGENCY	1 LOCAL
DATE REC	01/05/73	POTENCY	0000.0	TYPE AGENCY	1 LAW ENFORCEMENT
HOURS	02.0	BALLISTICS	NO		
WEEK ENDING	01/13/73			SUSPECTED FIRM	028 GEIGY
DILUENT					

LAB NO	A5846	REGIONAL LAB	WASHINGTON, D.C.	LOC. COLLECTED STATE/COUNTRY	DC WASHINGTON D.C.
BNDD FILE		SUSPECTED DRUG	1620 PHENDIMETRAZINE TARTRATE	BNDD REGION	
EXHIBIT	001B	AMT. REC	0001.00 PARAPHN	OTHER AGENCY	1 LOCAL
DATE REC	01/05/73	POTENCY	0000.0	TYPE AGENCY	1 LAW ENFORCEMENT
HOURS	01.5	BALLISTICS	NO		
WEEK ENDING	01/13/73				
DESCR.	001A				

1-30 BOOTLE CAP

167a

DRUG FOUND 1620 PHENDIMETRAZINE TARTRATE

WEEKLY LABORATORY ANALYSIS BY DRUGS
AS OF 11/30/72

PROCESSING DATE 12/15/72

LAB NO 2586
RND FILE
EXHIBIT 1
DATE REC 11/30/72
HOURS 02.0
WEEK ENDING 12/09/72

REGIONAL LAB MIAMI
SUSPECTED DRUG 1620 PHENMETRAZINE HCL
AMT. REC 0011.00 TABLET
POTENCY 0000.0
BALLISTICS NO

LOC. COLLECTED MIAMI
STATE/COUNTRY FL FLORIDA
RNOD REGION
OTHER AGENCY 1 LOCAL
TYPE AGENCY 1 LAW ENFORCEMENT

LAB NO 2587
RND FILE
EXHIBIT 2
DATE REC 11/30/72
HOURS 02.0
WEEK ENDING 12/09/72

REGIONAL LAB MIAMI
SUSPECTED DRUG 1620 PHENMETRAZINE HCL
AMT. REC 0015.00 TABLET
POTENCY 0000.0
BALLISTICS NO

LOC. COLLECTED MIAMI
STATE/COUNTRY FL FLORIDA
RNOD REGION
OTHER AGENCY 1 LOCAL
TYPE AGENCY 1 LAW ENFORCEMENT

168a

WEEKLY LABORATORY ANALYSIS BY DRUGS
AS OF 12/07/72

PROCESSING DATE 12/29/72

DRUG FOUND 1690 PHENDIMETRAZINE TARTRATE

LAB NO	25134	REGIONAL LAB	WASHINGTON, D.C.		LOC. COLLECTED	ANDREWS AFB
BNDD FILE		SUSPECTED DRUG	NONE		STATE/COUNTRY	MD MARYLAND
EXHIBIT	205A	AMT. REC	0020.00	TABLET	BNDD REGION	
DATE REC	10/27/72	POTENCY	0000.0		OTHER AGENCY	3 FEDERAL
HOURS	02.0	BALLISTICS	NO		TYPE AGENCY	1 LAW ENFORCEMENT
WEEK ENDING	12/16/72				SUSPECTED FIRM	124 TUTAG
AMOUNT						

168a

DRUG FOUND 1620 PHENDIMETRAZINE TARTRATE

WEEKLY LABORATORY ANALYSIS BY DRUGS
AS OF 12/31/72

PROCESSING DATE 01/18/73

LAB NO	A5840	REGIONAL LAB	WASHINGTON, D.C.	LOC. COLLECTED STATE/COUNTRY	DC WASHINGTON D.C.
BND FILE		SUSPECTED DRUG	1620 PHENDIMETRAZINE TARTRATE	BNDD REGION	
EXHIBIT	001A	AMT. REC	0001.00 TABLET	OTHER AGENCY	1 LOCAL
DATE REC	01/05/73	POTENCY	0000.0	TYPE AGENCY	1 LAW ENFORCEMENT
HOURS	02.0	BALLISTICS	NO		
WEEK ENDING	01/13/73			SUSPECTED FIRM	028 GEIGY
DILUENT					

LAB NO	A5846	REGIONAL LAB	WASHINGTON, D.C.	LOC. COLLECTED STATE/COUNTRY	DC WASHINGTON D.C.
BND FILE		SUSPECTED DRUG	1620 PHENDIMETRAZINE TARTRATE	BNDD REGION	
EXHIBIT	001B	AMT. REC	0001.00 PARAPHN	OTHER AGENCY	1 LOCAL
DATE REC	01/05/73	POTENCY	0000.0	TYPE AGENCY	1 LAW ENFORCEMENT
HOURS	01.5	BALLISTICS	NO		
WEEK ENDING	01/13/73				
DESCR. DATA			1-30 BOOTLE CAP		

17Ca

Phendimetrazine

DRUG FOUND 1620 PHENDIMETRAZINE TARTRATE

WEEKLY LABORATORY ANALYSIS BY DRUGS
AS OF 11/30/72

PROCESSING DATE 12/15/72

LAB NO 2586
BND FILE
EXHIBIT 1
DATE REC 11/30/72
HOURS 02.0
WEEK ENDING 12/09/72

REGIONAL LAB MIAMI
SUSPECTED DRUG 1620 PHENMETRAZINE HCL
AMT. REC 0011.00 TABLET
POTENCY 0000.0
BALLISTICS NO

LOC. COLLECTED MIAMI
STATE/COUNTRY FL FLORIDA
BNDD REGION
OTHER AGENCY 1 LOCAL
TYPE AGENCY 1 LAW ENFORCEMENT

LAB NO 2587
BND FILE
EXHIBIT 2
DATE REC 11/30/72
HOURS 02.0
WEEK ENDING 12/09/72

REGIONAL LAB MIAMI
SUSPECTED DRUG 1620 PHENMETRAZINE HCL
AMT. REC 0015.00 TABLET
POTENCY 0000.0
BALLISTICS NO

LOC. COLLECTED MIAMI
STATE/COUNTRY FL FLORIDA
BNDD REGION
OTHER AGENCY 1 LOCAL
TYPE AGENCY 1 LAW ENFORCEMENT

171a

WEEKLY LABORATORY ANALYSIS BY DRUGS
AS OF 12/07/72

PROCESSING DATE 12/29/72

DRUG FOUND 1620 PHENDIMETRAZINE TARTRATE

LAB NO 25134
DRUG FILE
EXHIBIT 05A
DATE REC 11/27/72
GRAMS 02.0
WEEK ENDING 12/16/72
AMOUNT

REGIONAL LAB WASHINGTON, D.C.
SUSPECTED DRUG NONE
ART. REC 0020.00 TABLET
POTENCY 0000.0
BALLISTICS NO

LOC. COLLECTED ANDREWS AFB
STATE/COUNTRY MD MARYLAND
BNDD REGION
OTHER AGENCY 3 FEDERAL
TYPE AGENCY 1 LAW ENFORCEMENT

SUSPECTED FIRM 124 TUTAG

1172d

DRUG FOUND 1620 PHENDIMETRAZINE TARTRATE

WEEKLY LABORATORY ANALYSIS BY DRUGS
AS OF 12/31/72

PROCESSING DATE 01/18/73

LAB NO	A5840	REGIONAL LAB	WASHINGTON, D.C.	LOC. COLLECTED	
BND FIL		SUSPECTED DRUG	1620 PHENDIMETRAZINE TARTRATE	STATE/COUNTRY	DC WASHINGTON D.C.
EXHIBIT	001A	AMT. REC	0001.00 TABLET	BNDD REGION	
DATE REC	01/05/73	POTENCY	0000.0	OTHER AGENCY	1 LOCAL
HOURS	02.0	BALLISTICS	NO	TYPE AGENCY	1 LAW ENFORCEMENT
WEEK ENDING	01/13/73				
DILUENT				SUSPECTED FIRM	028 GEIGY

LAB NO	A5846	REGIONAL LAB	WASHINGTON, D.C.	LOC. COLLECTED	
BND FIL		SUSPECTED DRUG	1620 PHENDIMETRAZINE TARTRATE	STATE/COUNTRY	DC WASHINGTON D.C.
EXHIBIT	001B	AMT. REC	0001.00 PARAPHN	BNDD REGION	
DATE REC	01/05/73	POTENCY	0000.0	OTHER AGENCY	1 LOCAL
HOURS	01.5	BALLISTICS	NO	TYPE AGENCY	1 LAW ENFORCEMENT
WEEK ENDING	01/13/73				
DESCR.	TA		1-30 BOOTLE CAP		

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FOUND 1620 PHENDIMETRAZINE TARTRATE — WEEKLY LABORATORY ANALYSIS BY DRUGS — PAGE
AS OF 11/30/72 — PROCESSING DATE 12/15/7

LAB NO	2586	REGIONAL LAB	MIAMI	LOC. COLLECTED	MIAMI
BNDD FILE		SUSPECTED DRUG	1620 PHENMETRAZINE HCL	STATE/COUNTRY	FL FLORIDA
EXHIBIT	1	AMT. REC	0011.00 TABLET	BNDD REGION	
DATE REC	11/30/72	POTENCY	0000.0	OTHER AGENCY	1 LOCAL
HOW	02.0	BALLISTICS	NO	TYPE AGENCY	1 LAW ENFORCEMENT
WEEK ENDING	12/09/72				

LAB NO	2587	REGIONAL LAB	MIAMI	LOC. COLLECTED	MIAMI
BNDD FILE		SUSPECTED DRUG	1620 PHENMETRAZINE HCL	STATE/COUNTRY	FL FLORIDA
EXHIBIT	2	AMT. REC	0015.00 TABLET	BNDD REGION	
DATE REC	11/30/72	POTENCY	0000.0	OTHER AGENCY	1 LOCAL
HOW	02.0	BALLISTICS	NO	TYPE AGENCY	1 LAW ENFORCEMENT
WEEK ENDING	12/09/72				

DRUG CODE 1620 PHENDIMETRAZINE TARTRATE

WEEKLY LABORATORY ANALYSIS BY DRUGS
AS OF 12/07/72

PROCESSING DATE 12/29/72

LAB NO	25134	REGIONAL LAB	WASHINGTON, D.C.	LOC. COLLECTED	ANDREWS AFB
BND FILE		SUSPECTED DRUG	NONE	STATE/COUNTRY	MD MARYLAND
EXHIBIT	005A	AMT. REC	0020.00 TABLET	BNDD REGION	
DATE REC	10/27/72	POTENCY	0000.0	OTHER AGENCY	3 FEDERAL
ROUTE	02.0	BALLISTICS	NO	TYPE AGENCY	1 LAW ENFORCEMENT
WEEK ENDING	12/16/72				
DILUENT				SUSPECTED FIRM	124 TUTAG

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DRUG FOCUS 1620 PHENDIMETRAZINE TARTRATE

WEEKLY LABORATORY ANALYSIS BY DRUGS
AS OF 12/31/72

PROCESSING DATE 01/18/73

LAB NO	A5840	REGIONAL LAB	WASHINGTON, D.C.	LOC. COLLECTED STATE/COUNTRY	DC WASHINGTON D.C.
BNDD FILE		SUSPECTED DRUG	1620 PHENDIMETRAZINE TARTRATE	BNDD REGION	
EXHIBIT	001A	AMT. REC	0001.00 TABLET	OTHER AGENCY	1 LOCAL
DATE REC	01/05/73	POTENCY	0000.0	TYPE AGENCY	1 LAW ENFORCEMENT
HOURS	02.0	BALLISTICS	NO		
WEEK ENDING	01/13/73			SUSPECTED FIRM	028 GEIGY
DILUENT					

LAB NO	A5846	REGIONAL LAB	WASHINGTON, D.C.	LOC. COLLECTED STATE/COUNTRY	DC WASHINGTON D.C.
BNDD FILE		SUSPECTED DRUG	1620 PHENDIMETRAZINE TARTRATE	BNDD REGION	
EXHIBIT	001B	AMT. REC	0001.00 PARAFFIN	OTHER AGENCY	1 LOCAL
DATE REC	01/05/73	POTENCY	0000.0	TYPE AGENCY	1 LAW ENFORCEMENT
HOURS	01.5	BALLISTICS	NO		
WEEK ENDING	01/13/73				
DESCR.	1-30 BOOTLE CAP				

176a

DRUG FOUND 1620 PHENDIMETRAZINE TARTRATE

WEEKLY LABORATORY ANALYSIS BY DRUGS
AS OF 11/30/72

PROCESSING DATE 12/10/72

LAB NO 2586
SUBMITTED
EXHIBIT 1
DATE REC 11/30/72
HOURS 02.0
WEEK ENDING 12/09/72

REGIONAL LAB MIAMI
SUSPECTED DRUG 1620 PHENMETRAZINE HCL
AMT. REC 0011.00 TABLET
POTENCY 0000.0
BALLISTICS NO

LOC. COLLECTED MIAMI
STATE/COUNTRY FL FLORIDA
BNDD REGION
OTHER AGENCY 1 LOCAL
TYPE AGENCY 1 LAW ENFORCEMENT

LAB NO 2587
SUBMITTED
EXHIBIT 2
DATE REC 11/30/72
HOURS 02.0
WEEK ENDING 12/09/72

REGIONAL LAB MIAMI
SUSPECTED DRUG 1620 PHENMETRAZINE HCL
AMT. REC 0015.00 TABLET
POTENCY 0000.0
BALLISTICS NO

LOC. COLLECTED MIAMI
STATE/COUNTRY FL FLORIDA
BNDD REGION
OTHER AGENCY 1 LOCAL
TYPE AGENCY 1 LAW ENFORCEMENT

177a

Phendimetrazine

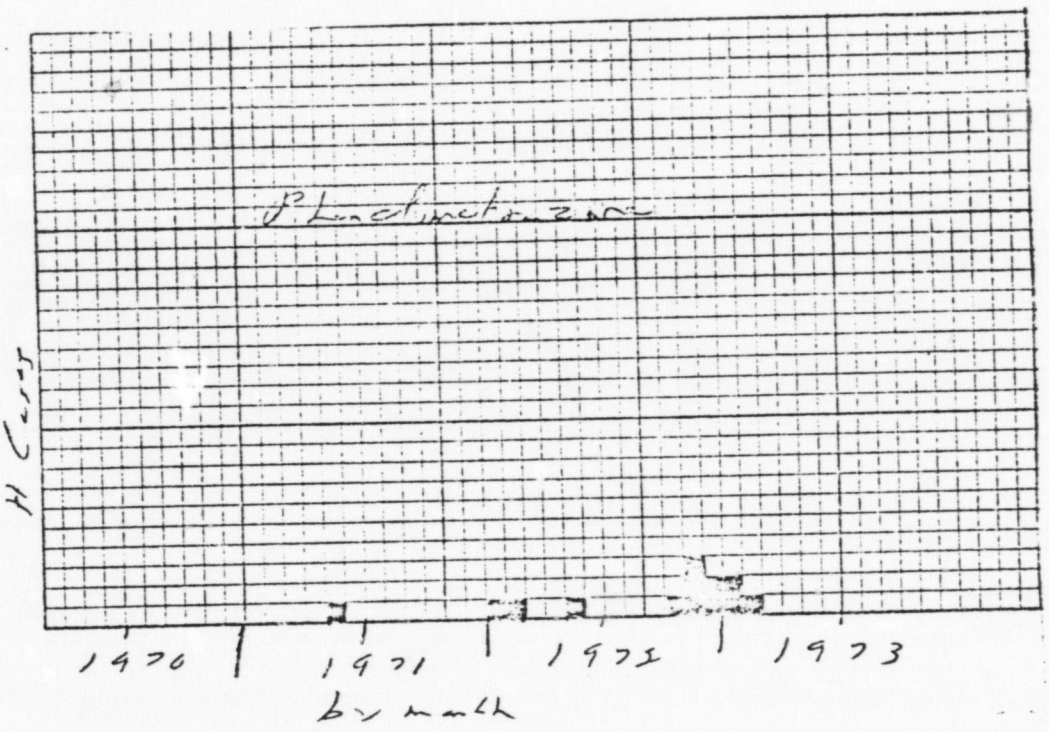
BNDD Laboratory Analysis from 1 July, 1970 to Date

Date Received	Lab #	BND Case #	Quantity Received	Suspected Manufacturer	Location Collected	Exhibit #
5/27/71	9013	J1-710029	75 tab	Ayerst	New Orleans, Louisiana	Ex. 22
2/18/72	6260	---	4 tab	Ayerst	Chicago, Illinois	Ex. 1
1/21/72	A0339	---	33 tab	Ayerst	Washington, D.C.	Ex. 1
5/14/72	788	G1-720073	785 tab	---	Miami, Florida	Ex. 36
10/27/72	25134	---	20 tab	Tutag	Andrews AFB, Maryland	Ex. 5A
11/6/72	2348	J1-72D541	100 tab	---	New Orleans, Louisiana	Ex. 28
	2349	"	100 tab	---	"	Ex. 29
	2353	"	100 tab	---	"	Ex. 33
11/30/72	2586	---	11 tab	---	Miami, Florida	Ex. 1
11/30/72	2587	---	15 tab	---	Miami, Florida	Ex. 2
1/5/73	A5840	---	Syringe needle 0.01 Paraphn.	---	Washington, D.C.	Ex. 1C

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Phendimetrazine con't.

Date Received	Lab #	BND Case #	Quantity Received	Suspected Manufacturer	Location Collected
1/5/73	A5840	---	1 tab	Geigy	Washington, D.C.
	A5846	---	Bottle Cap 1 Paraphn.	---	"
2/20/73	11284	I1730071	390 tab	---	Chicago, Illinois
12/29/72	17531	---	21 tab	---	Mesquite, Texas
12/29/72	17531	---	12 tab	---	Mesquite, Texas



P Lindinetrazine, Laboratory Analysis, Number of cases by date sample was received

Summary of circumstances associated with acquistion of drug

PHENDIMETRAZINE

J-1-71-0029 (5/27/71) -- In this case, a practicing pharmacist was distributing diverted pharmaceutical drugs to the southeastern Louisiana area. The defendant was arrested as he was enroute to deliver some drugs to BNDD agents. A search warrant was executed at his residence. Of the 3200 dosage units seized, 75 were phendimetrazine tablets.

G-1-72-0073 (5/14/72) -- Defendant was a physician who was illegally selling and dispensing amphetamines and barbiturates without medical examination on doctor-patient relationship. In May of 1972, 785 tablets of phendimetrazine were seized after arresting the defendant.

J-1-72-D541 (11/06/72) -- An agent was introduced to a pharmacist who wanted to sell Desoxyn, Biphetamine and Didrex. In the course of the investigations 1090 tablets and capsules of proprietary preparations of amphetamine and methamphetamine were purchased or seized as were 100 Ritalin and Didrex tablets, 200 Ionamin capsules, 300 phendimetrazine containing tablets or capsules, 6.9 grams of cocaine; 402 tablets or capsules of amphetamine - barbiturate proprietary combinations, 829 proprietary barbiturate containing tablets or capsules, 213 Valium and 194 Quaalude tablets, 400 codeine containing tablets and 23 grams of morphine sulfate. 100 tablets of a diuretic were among the drugs purchased.

Laboratory -- #2586 and #2587 -- Two (2) laboratory cases were samples received in November 1972 from the Hialeah Crime Laboratory in Miami, Florida. The samples were purchased by a detective and consisted of eleven and fifteen tablets which were identified as phendimetrazine.

I-1-73-0071 (2/20/73) -- A cooperating individual was able to purchase 390 tablets which were alleged to be amphetamine. Upon chemical analysis, the drug was determined as phendimetrazine. On February 23rd, the informant could buy 100,000 "black capsules" but he would have to purchase at least 10,000 of 30,000 phendimetrazine tablets they had.

Summary of Letters Documenting Phendimetrazine Abuse

PHENDIMETRAZINE

December 1972

"Pnendimetrazine has been found in the New Jersey State Police Laboratory. Recently a thousand light green tablets were seized." The drug was identified by Infrared and Mass Spectroscopy.

January 1973

Three samples have been identified as phendimetrazine in the Pennsylvania State Police Crime Laboratory at Harrisburg. Ultraviolet and Infrared Spectra, thin layer chromatography, and chemical color tests were utilized to identify phendimetrazine. Upon receiving further samples, the identity of the excipients resembled the 35 mg "Bacarate" brand of phendimetrazine tartrate distributed by S.J. Tutag and Company, Detroit, Michigan.

February 1973

Ballistic examination by SCIL was completed on capsules submitted by the Mississippi Bureau of Narcotics. The capsules contained phendimetrazine tartrate but could not be identified as to manufacturing source.

February 1973

Mississippi Crime Laboratory were having a problem with an exhibit. The capsules, resembling Dexedrine, were bought by narcotic agents who were told they were amphetamines. Chemical tests were giving results which were dissimilar to those of amphetamine or any other drug they were familiar with. Examination by the Special Testing and Research Laboratory resulted in the findings that the capsules contained phendimetrazine tartrate but could not be identified as to manufacturing source.

February 1973

Phendimetrazine has also been reported by the Philadelphia Police Chemistry Laboratory. In one seizure ten (10) capsules were found to contain the drug. They were the same size as the standard amphetamine sulfate capsules but unimprinted, conventionally shaped and contained orange and white pellets.

Summary of Letters Documenting Phendimetrazine Abuse (continued)

PHENDIMETRAZINE

March 8, 197[illegible]

Within the past 30 days, the Northern Illinois Police Crime Laboratory has received a quantity of phendimetrazine as double scored pink tablets and double scored white tablets. Exhibits have also been processed which were in powder form.

March 8, 1973

The Drug Analysis Laboratory of the Pharmacology Department of the University of Louisville School of Medicine has frequently identified phendimetrazine tablets confiscated in this area. The tablets were not Ayerst Plegine but are plain white, well made tablets.

March 20, 1973

A letter was received from the Washington State Board of Pharmacy recommending the control of phendimetrazine under the Controlled Substances Act. In a recent case, over a million dosage units of this drug were confiscated. Further information indicated that the same practitioner has 1.4 million dosage units in storage, awaiting the outcome of the first case. The practitioners feel that this drug will give the same anorexic effects as amphetamines or amphetamine-like drugs.

Phentermine

BNDD Laboratory Analysis from 1 July, 1970 to Date

Date Received	Lab #	BND Case #	Quantity Received	Trade Name	Suspected Manufacturer	Location Collected	Exhibit #
12/4/70	6968	---	2	---	Strasenburg	Lake Charles, Louisiana	---
1/12/71	12386	---	4	---	---	Takoma Park, Maryland	Ex. 18
3/22/71	14444	---	1	---	---	Arlington, Virginia	Ex. 1
4/12/71	8432	---	2	---	---	Carrollton, Texas	Ex. 2
8/16/71	18777	---	0.03	---	---	Washington, D.C.	Ex. 1
10/4/71	4945	C1710301	1	---	---	New York, New York	Ex. 3B
12/3/71	5631	B1710124	84	---	---	Farmingham, Mass.	---
1/25/72	6084	C3720021	23	---	Strasenburg	Livingston, New Jersey	Ex. 13A
2/8/72	6131	---	50	Ionamin	Strasenburg	Washington, Ill.	Ex. 4
			100	"	"	" "	Ex. 5
			100	"	"	" "	Ex. 6
			15	"	"	" "	Ex. 7A

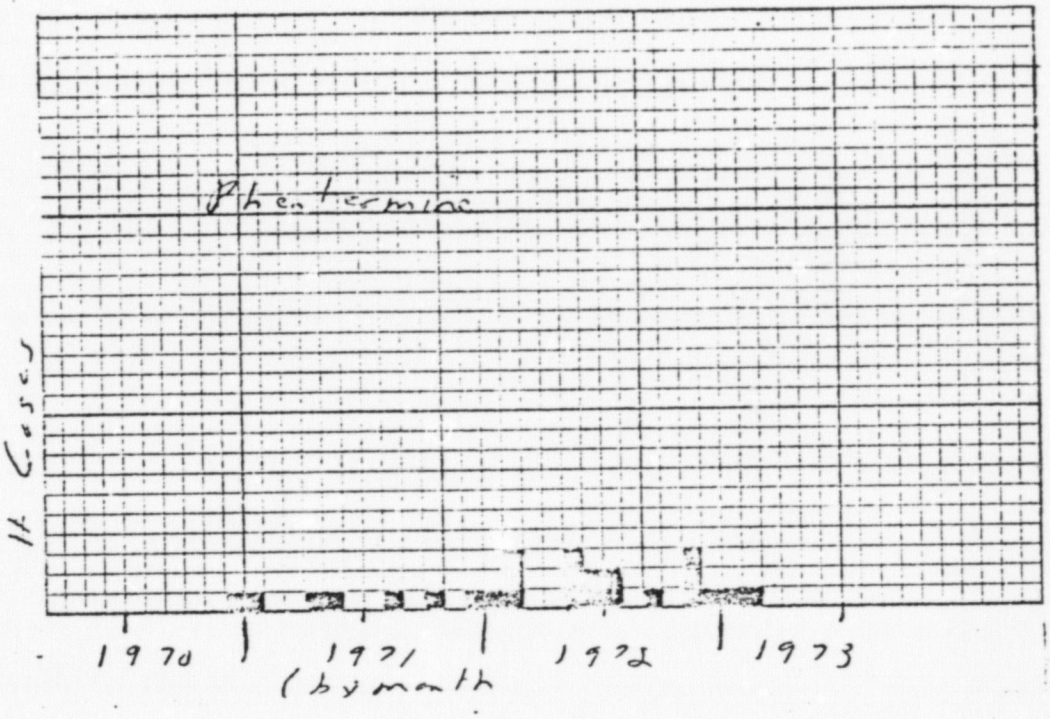
Phentermine cont't.

Date Received	Lab #	BND Case #	Quantity Received	Trade Name	Suspected Manufacturer	Location Collected	Exhibit #
2/10/72	6163	---	400	---	Strasenburg	Peoria, Ill.	Ex. 5
			139	---	"	" "	Ex. 13
2/25/72	6514	C1720101	22	---	Strasenburg	New York, N.Y.	Ex. 4
5/17/72	794	---	1	---	Strasenburg	Atlanta, Georgia	Ex. 2B
5/25/72	907	J4720009	6	---	---	Nauvoo, Alabama	Ex. 2
5/30/72	7402	I1710224	1	---	---	Calumet City, Illinois	Ex. 4
6/27/72	14612	M3720033	14.01g	(powder)	---	Houston, Texas	Ex. 1
	14613		13.63g	"	---	" "	Ex. 2
	14614		17.04g	"	---	" "	Ex. 3
	14615		14.43g	"	---	" "	Ex. 4
	14616		0.86g	"	---	" "	Ex. 5
	14617		0.43g	"	---	" "	Ex. 6
6/28/72	14671	---	2	---	---	Roswell, N.M.	---
7/10/72	07863	---	42	Ionamin	Strasenburg	Davenport, Iowa	Ex.1A3A
	07863	---	33	"	"	" "	Ex.1A3B
	07863	---	7	"	"	" "	Ex. 2A2
7/13/72	24514	---	7	---	Strasenburg	P.G. County, Maryland	Ex. A

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Phentermine con't.

Date Received	Lab #	BND Case #	Quantity Received	Trade Name	Suspected Manufacturer	Location Collected	Exhibit #
9/27/72	16102	N3720034	3	---	Strasenburg	Albuquerque, N.M.	Ex. 20C5
11/6/72	2350	J172D541	100	---	---	New Orleans, Louisiana	Ex. 30
	2351		100			"	Ex. 31
11/14/72	10162	C1720495	2	---	Strasenburg	New York, N.Y.	Ex. 11C
11/27/72	17044	---	37	---	---	Mesquite, Texas	Ex. 1
12/14/72	25511	---	2	---	Strasenburg	Montgomery Co., Maryland	Ex. 7
1/19/73	B0279	---	5	---	Strasenburg	Washington, D.C.	Ex. 2
2/27/73	11501	C173X007	2	---	Strasenburg	New York, N.Y.	Ex. 7



Phentermine, Laboratory Analysis, number of cases by date sample was received

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Summary of circumstances associated with acquisition of drug

PHENTERMINE

C-1-71-0301 (10/4/71) -- One (1) capsule of phentermine was taken from of one of four individuals suspected of trafficking in cocaine.

B-1-71-0124 (12/3/71) -- BNDD agent, posing as a user of Speed, presented himself to a physician suspected of illicit prescribing practices. In the course of the investigation approximately 12 prescriptions were written involving seven drugs. In addition, the physician sold the agent 12 free sample packs, each containing seven Ionamin 30 mg. capsules.

C-1-72-0021 (1/25/72) -- Suspected clandestine Mescaline laboratory was raided. Eighteen capsules of phentermine were found in a kitchen cupboard.

C-1-72-0101 (2/25/72) -- Twenty-two (22) capsules of phentermine were found on a suspected heroin pusher along with 109 grams of cut heroin and 1½ tablets of methadone.

J-4-72-0009 (5/25/72) -- An informant established a contact who was dealing in large quantities of "blacks" (RJS Biphetamine capsules). Negotiations were entered into for the purchase of large quantities of "blacks." The dealer offered to sell "yellows" because "blacks" were scarce. Informant refused but did purchase six "yellows" as a sample. SCIL determined the "yellows" to be Ionamin capsules manufactured by R.J. Strassenburgh Company.

1-1-71-0024 (5/30/72) -- Negotiations were entered into for the purchase of "amphetamines." Suspect agreed to deliver 10,000 Biphetamine capsules and 2,100 Benzedrine tablets. Suspect gave agent one(1) Ionamin capsule and two (2) Serax tablets as samples of other drugs which he could supply in large quantities. Suspect and his source were arrested and 6,150 Biphetamine capsules and 2204.5 tablets of Benzedrine were seized.

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Summary of circumstances associated with acquisition of drug

PHENTERMINE (continued)

M-3-72-0033 (6/27/72) -- A chemical manufacturer notified BNDD that a company had ordered precursors and reagents which might be used for the manufacture of amphetamine. BNDD determined that no such company existed and raided the house into which the order had been taken. Precursors, reagents, powder drying on mirrors, in a bowl and in a purse were seized. Analysis of the powder showed that it was phentermine. In reading the case report it was noticed that α(α-dimethylphenthylamine (phentermine) was one of the "precursors" ordered from the licit manufacturer.

N-3-72-0034 (9/27/72) -- During the execution of a search of the premises occupied by individuals suspected of possessing marihuana for distribution, quantities of marihuana, peyote, LSD, cocaine, amphetamine and phenobarbital were seized as were tablets or capsules provisionally identified as Vistaril, Darvon, Darvon-65, Vivactil, Valium, Equanil, Dalmane, Combid, Lasix, Robaxin, Silian, Valpin-P.B., Thyroid, Symthroid, Desoxyn, and Ionamin.

J-1-72-D541 (11/06/72) -- An agent was introduced to a pharmacist who wanted to sell Desoxyn, Biphetamine and Didrex. In the course of the investigations 1090 tablets and capsules of proprietary preparations of amphetamine and methamphetamine were purchased or seized as were 100 Ritalin and Didrex tablets, 200 Ionamin capsules, 300 phendimetrazine containing tablets or capsules, 6.9 grams of cocaine; 402 tablets or capsules of amphetamine - barbiturate proprietary combinations, 829 proprietary barbiturate containing tablets or capsules, 213 Valium and 194 Quaalude tablets, 400 codeine containing tablets and 23 grams of morphine sulfate. 100 tablets of a diuretic were among the drugs purchased.

C-1-72-0495 (11/14/72) -- Following the arrest of three (3) individuals involved in the sale of one (1) kilo of heroin, three (3) individuals tangential to the case were arrested. One (1) of the latter individuals, when asked if he had any narcotic or drug substance in his apartment, presented

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Summary of circumstances associated with acquisition of drug

PHENTERMINE (continued)

C-1-72-0495 (11/14/72) -- the agent with approximately 10 grams of marihuana and an envelope containing 2 phentermine, 1 amphetamine (Biphetamine), 1 secobarbital - pentobarbital containing capsule, 1/2 tablet containing amphetamine and methamphetamine and 1 tablet containing LSD.

Laboratory Number 17044 (11/27/72) -- Non-federal case - limited information available. Individual charged with possession with intent to sell. SCIL not aware that any other drug or exhibit associated with case

C-1-73-X007 -- File incomplete. Information available indicates that during a search of premises occupied by two (2) arrested individuals, a travel bag was found which contained 2 phentermine, 2 alleged amphetamine, 3 phencyclidine, 64 doxepin containing capsules; 570 LSD, and 57 methadone containing tablets and 16½ assorted tablets and capsules of alleged barbiturates.

JKLawrence/jg/4/10/

March 16, 1973

Mr. Ernest A. Carabillo
Chief, Drug Control Division

William W. Vodra
Assistant Chief Counsel

Non-Controlled Anorectic Drugs

Since our meeting on Tuesday I have had a chance to discuss this matter with both Mr. Miller and Mr. Rosthal and to review the draft of the memorandum of meeting on March 13.

Without going into great detail regarding the memorandum of meeting, I don't believe that the introductory two pages provide sufficient information to present to the Drug Control Committee or to the Director for decision making. Unless I misunderstood the remarks of your staff on Tuesday, I believe they said that there was sufficient data to show that all of the stimulant anorectics (except possibly Mazindol) are sufficiently similar in their chemical and pharmacological properties to make it "reasonable to assume that there may be significant diversion from legitimate channels, significant use contrary to or without medical advice" and other forms of abuse and misuse at increasing levels as the amphetamines become less available. This statement would bring the stimulant anorectics within the definition of "potential for abuse" quoted in the legislative history by the House Committee in referring to regulations promulgated under DACA law. It would therefore seem inaccurate to state that SCID "has found only scanty data pertinent to their potential for abuse."

I also believe that it would be more accurate to state that there has been preliminary information gathered that indicates recent diversion of four of the marketed

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anorectics by physicians, with the express purpose of supplying stimulants when amphetamines were not easily available.

The sentence regarding HEW's information is misleading in that it suggests that BNDD will have to gather the remaining medical and scientific data from our own resources. It is my understanding that the material given to BNDD was the summarization of the NDA applications filed with FDA. Since it is their opinion that these drugs are medically and pharmacologically similar to each other and to amphetamines and since their opinion is binding on BNDD, the crucial test is not whether the information [illegible] is sufficient; and will be given in a hearing to control these drugs. I am attempting to contact Dr. Scoville right now to get an answer to that question. If the answer is affirmative, then I think the Drug Control Committee should be informed that this information is available and is binding on BNDD.

Regarding selection of the options, Chief Counsel's office is of the opinion that action now is important for a variety of reasons. It is not crucial at this time to select between options 1, 2 and 3 (which are the most realistic alternatives) until we have commenced discussions with the drug companies and get a better feeling for the possibilities of having and winning hearings. We should enter discussions from the standpoint of the FDA recommendation in indicating a general Bureau philosophy that these drugs should be controlled [illegible] indicate a high probability of hearings and therefore will require an extensive work up by SCI and ENA of data now in the hands of FDA and federal, state and local agencies in the field, then we can consider other alternatives.

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3.

It would seem unwise to delay action when we must admit realistically that we are going to control these drugs at some point in the future. It is my belief that we politically must control the drugs at some time (making option 3 of no control is unrealistic), that we will not control the drugs in Schedule II because at this time we cannot sustain the case (that, option 4 is unsustainable), that marijuana would not be placed in Schedule III (making option 3 implausible), that delay in action will generate an increasing requirement for BNDD manpower to be expended to control those items in Schedule III and IV at a later date (making option 7 undesirable) and that the remaining options are 1, 2 and 5. I further believe it would be unwise to remove [illegible] with the companies by maintaining silence on any one or more of these options. Furthermore, a decision on any one of these three options at this time (particularly options 2 and 5) might be undone by developments reflected by intelligence continuing to come in from the field during the period of time we were negotiating with the companies.

One final matter that I believe must be brought to the Drug Control Committee's attention is the fact that FDA is voluntarily withholding the New Drug Applications on three new products to support our drug control efforts. The only [illegible] is that we have commenced action to control and until that action is completed these drugs should not be made available to the American people. If BNDD delays commencing control proceedings, the FDA position becomes untenable and they will have to permit the marketing of these three drugs.

Form DJ-150
Ed. 4-26-65)

UNITED STATES GOVERNMENT

DEPARTMENT OF JUSTICE

Memorandum

194a

TO : Files

DATE: April 12, 1973

FROM : William W. Vodra
Assistant Chief Counsel

SUBJECT: Ionamin

The following information regarding diversion of Ionamin was gathered during February 26, 27, and 28 by William Vodra upon contacting various BNDD field offices and reviewing investigative files:

1. Thefts. Region 11 (Texas and Oklahoma) began monitoring theft reports from pharmacies early in 1973 because of an increasing appearance of noncontrolled drugs in the theft reports. It should be noted that thefts of noncontrolled drugs are not required to be reported to BNDD; therefore, the data is not complete but merely indicative of the activities. Generally, the noncontrolled drugs were included in reports of thefts that included other controlled substances. The following quantities of Ionamin were reported as stolen during the period of September 1, 1972, to February 15, 1973.

September	500 tablets
October	570 tablets
November	400 tablets
December	0
January	100 tablets
February	0
	1,570 tablets

This suggests that Ionamin is a target for persons stealing abusable drugs from pharmacies for illicit sale or use purposes.

2. Conversations with a BNDD/DALE agent in one major southern city indicated that the agent had seen Ionamin at least six times in the illicit street traffic in the

last few months. No purchases were made and no reports were filed because Ionamin is not a controlled substance. However, the agent reported that Ionamin is selling for $0.50 a tablet in the city and, while not widespread in the street, it is available to anyone desiring it.

3. Criminal Case No. 1 An investigative case file on a defendant who has been arrested but not yet tried indicates that the defendant, a registered physician, was selling large quantities of controlled drugs. Agents made buys on seven occasions prior to the arrest of the defendant. The pattern and appearance of Ionamin is significant.

Purchase Number	Drug Bought	Quantity
#1 (last quarter, 1972) Total price: $300	Biphetamine	400 d.u.
	Desoxyn	400 d.u.
	Tuinal	100 d.u.
	Nembutal	100 d.u.
	Talwin	10 ml.
#2 (Six days after #1) Total price: $500	Biphetamine	200 d.u.
	Tuinal	300 d.u.
	Desoxyn	100 d.u.
	Preludin	100 d.u.
#3 (Eight days after #2) Total price: $1,300	Biphetamine	325 d.u.
	Seconal	940 d.u.
	Pentobarbital	4,865 d.u.
	Dexedrine	575 d.u.
	Preludin	100 d.u.
	Dalmane	500 d.u.
	Demerol	30 cc.
#4 (Seven days after #3) Total price: no charge	Seconal	1,000 d.u.
	Tuinal*	500 d.u.
	Nembutal*	500 d.u.
	Quaalude*	3,000-5,000 d.u.

* Offered for sale but not purchased by Agents.

3.

Purchase Number	Drug Bought	Quantity
#5 (Six days after #4) Total price: $2,200	Ritalin	5,000 d.u.
	Nembutal	300 d.u.
	Doriden	100 d.u.
	Preludin	388 d.u.
	Bacarate	2,000 d.u.
	Terpinhydrate with Codeine	161 bottles (4 oz. ea.)
	Codinal	96 bottles (4 oz. ea.)
	Cheracol	72 bottles (2 oz. ea.)
	Asthec-G (Codeine)	3,000 d.u.
#6 (One day after #5) Total price: $700	Ionamin	1,600 d.u.
	Bacarate	2,000 d.u.
#7 (Approximately 12 weeks after #6) Total price: $15,000	Ionamin	2,000 d.u.
	Bacarate	6,000 d.u.
	Ritalin	300 d.u.
	Obetrin-LA	500 d.u.
	Desoxyn	500 d.u.
	Biphetamine	2,075 d.u.
	Quaalude	1,400 d.u.
	Placidyl	388 d.u.
	Doriden	1,000 d.u.
	Nembutal	1,000 d.u.
	Nouldar	400 d.u.
	Talwin	110 vials (10 ml.ea.
	Demerol	2 vials (30 cc ea.
	Paregoric	3 pints
	Narcotic Cough Formula	72 bottles (4 oz. ea.)
	PAC Compound (Codeine	3,000 d.u.

During purchase #4, Ionamin was offered to the agent. The investigative report read as follows:

> "Dr. I--- then wanted to know if we [the agents] could sell some Ionamin. He said that they were almost as good as Biphetamine 20 and that he could sell them and cover the sales easily. Dr. I--- then asked X--- [an independent illicit drug dealer introduced to the agents by Dr. I--- for the purpose of supplying the agents with heroin, cocaine, marihuana, and dangerous drugs smuggled in from Mexico] how he like them? X--- stated that, "They are good, I took two and I had a hard time getting to sleep" Dr. I--- stated "Yeah, I took one and I thought they were good." Dr. I--- left the office.

Seven days later the physician provided the agents with 1,600 Ionamin and another 2,000 Ionamin 12 weeks after that.

4. Criminal Case No. 2 Another investigation involving a physician commenced in the last quarter of 1972. An agent (Agent A---) purchased 30 Biphetamine. One month later the agent purchased 30 Biphetamine and 70 Ionamin and a prescription for 30 Seconal. The investigative report contains the following paragraph regarding this purchase:

> Agent A--- asked Dr. J--- what about Ionamin. Dr. J--- advised him that the regulations on them were not so bad but stated that they were no good but he would give the agent seven of them to let one of his girls try them out. [The agent had represented that he was a pimp and wished to have his girls take amphetamines to stay awake.]

Ten days later, Agent A--- purchased 105 Ionamin and two prescriptions for Biphetamine. Approximately three weeks later, Agent A--- and another agent purchased a total of 119 Ionamin, [56 Ionamin (15 mg.) and 63 Ionamin (30 mg.)] together with four prescriptions for 30 Biphetamine each and one prescription for 30 Seconal. (The physician also sold six prescriptions for Biphetamine to other agents on 2 other occasions.)

5. Criminal Case No. 3 This is an active investigation involving a physician commenced in 1973. Agent F--- approached Dr. K--- for the purpose of buying Biphetamine 20 or other amphetamines. The investigative case file reads as follows:

> "Dr. K--- advised that the narcotic people told him not to write prescriptions for amphetamines as the narcotic people were making trouble for him and advised Agent F--- that he could give a prescription for Ionamin as it would do the same thing [i.e., keep him awake]."

The physician then sold the agent two prescriptions for 30 Ionamin each. (Prior to his conversation with the physician, the agent had overheard a young hippie-type individual attempt to buy amphetamines from the doctor; the doctor refused to write for anything but Ionamin and no agreement was reached between the youth and the doctor.) Approximately three and half weeks later, two more agents, Agents G--- and H--- purchased a total of three prescriptions for 30 Ionamin a piece. One week later Agents G--- and M--- visited the doctor; Agent G--- purchased a prescription for 30 Ionamin, while Agent M--- purchased a prescription for 100 Ritalin.

6. Criminal Case No. 4 This investigation also involves a physician. Agent P--- approached Dr. N--- in late 1972 and purchased a prescription for 36 Biphetamine. Eleven days later the agent purchased another prescription for 36 Biphetamine and a prescription for 36 Desoxyn. Six weeks later, the agent attempted to make a third purchase for the physician. The investigative file reads as follows:

> "Dr. N--- stated that he could not write a prescription for amphetamine any more. Agent A--- asked Dr. N--- if there was any substitute that he, Dr. N--- could give."

The agent then purchased two prescriptions for 36 Ionamin each and one prescription for 36 Doriden.

7. Criminal Case No. 5 A physician was arrested recently for selling Obedrin LA and Biphetamine to agents. At the time of the physician's arrest all stocks of controlled drugs were seized. The doctor continued medical practice pending the trial. In January of 1973, the physician reported the theft from his office of 1,000 Ionamin and 8,000 phendimetrazine tablets, indicating a shift in his activities from amphetamines to Ionamin and other noncontrolled anorectics.

IONAMIN - SIGNIFICANT CASES

Case #G5-73-0004

On March 2, 1973, Special Agents and an informant drove to the area of a pharmacy located in Puerto Rico. After searching the informant he was given $700 official Government funds for the purchase of mannite for cutting heroin and/other FOR PURCHASING drugs. While under surveillance by the Agents the informant entered the pharmacy and paid for the mannite which was to be delivered later and purchased 10 x 100 tablet bottles of Ionamin for $200.

Note: These 1,000 tablets were returned later to the pharmacy when they were determined to be non-controlled substances and the $200 was returned to the informant.

M2-73-0024

On March 22, 1973, an informant notified Region 11 Agents that he knew an individual who procured some 40,000 - 100,000 capsules ~~of~~ FROM an unidentified stimulant from a source in El Paso, Texas and subsequently distributes them to truck stops

between San Antonio, Texas and Washington, D. C. The informant stated that the defendant was currently in possession of 400 - 500 of these capsules. On this same date the informant surrendered 70 Ionamin capsules to the Agents, and stated they were part of what the defendant had in his possession. Later that day the defendants vehicle was searched and 405 Ionamin capsules were seized.

Note: These capsules bore "RJS". It is ENA's understanding that for the last year or so Domestic Strasenburgh products were identified with the Pennwalt Corp. symbol and Mexican Strasenburgh products were identified with the "RJS" symbol.

LOCAL CASE

On March 3, 1973, the Winston-Salem Police Department executed a search warrant and arrested one individual and seized 700 Ionamin tablets along with other drugs.

Region 1

Lab data at Massachusetts Department of Public Health shows a total of 27 samples of Ionamin analyzed since June 1972.

March 19, 1973, Massachusetts State Police seized 411 capsules of Ionamin from unnamed defendant.

Region 2

Reports no availability of Ionamin.

Region 3

Reports no availability of Ionamin.

Region 4

State of North Carolina has analyzed 25 exhibits from illicit traffic since June 1972.

Charlotte, North Carolina Police have had approximately six cases since June 1972, but no records kept on non-controlled substances.

Region 5

Two exhibits of Ionamin have been examined by Florida State authorities. These were very small quantities.

See attached significant cases.

Region 6

The Michigan DIU has initiated four cases in which purchases of Ionamin were made. Total Ionamin involved 150 dosage units - largest purchase 50 dosage units.

Three samples of Ionamin analyzed by Plymouth, Michigan State Police Lab. involving approximately 450 dosage units of Ionamin.

The Detroit Police Department reported the hijacking of a truck load of Ionamin, however, total amount of Ionamin involved was not available.

Kentucky State Police have analyzed 75,400 Ionamin capsules during the last year.

The Columbus, Ohio District Office has one case pending concerning the dispensing of Ionamin by a nurse without a prescription. The District

Office also reports one overdose incident from Ionamin. The drug is reported as readily available on the streets of Columbus.

The Cleveland District Office reports local authorities have made five or six purchases totaling 100 dosage units of Ionamin and that street use of the drug is increasing in the area.

On May 29, 1973, Cincinnati Police Department arrested one individual in possession of five Ionamin capsules.

Summary: Region 6 - 23 cases of purchases or seizures.

Region 7

Reports no availability of Ionamin.

Region 8

Region 10

On April 21, 1973, the Missouri County Sherriffs Department, Charleston, Missouri, seized 1,450 dosage units of Ionamin from an unnamed defendant.

Region 11

Texas DIU reports significant increase of practitioners writing R_x's for Ionamin in the last eight months.

DIU has purchased or seized Ionamin in ten instances since November 22, 1972, involving approximately 4,000 dosage units.

Region 12

Reports no availability of Ionamin.

Region 13

Reports no availability of Ionamin.

Region 14

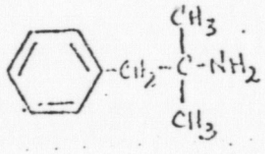
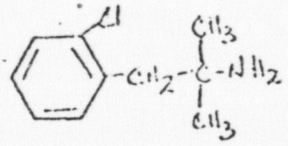
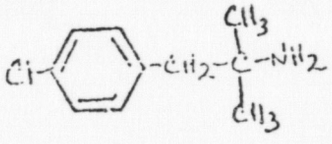
COMPOSITE TABLE OF COMMON PHARMACOLOGIC PROPERTIES OF ANOREXIGENIC DRUGS

Drug Name	Potency as CNS Stimulant	Motor Activity	Blood Pressure	Tachyphylaxis	Tolerance to Anorexigenic Effect	Norepinephrine Release	Sug Elevation	Lipid Mobilization	Urinary Post Administration Test	Adapted Human Abuse	Level of Reported Effect Amphetamine or Equiv.
l-amphetamine	50	increased	elevated	present	yes	yes	no	yes	positive	yes	yes
d-amphetamine	100	increased	elevated	present	yes	yes	no	yes	positive	yes	yes
methamphetamine	200	increased	elevated	present	yes	yes	no	yes	positive	yes	yes
benzphetamine	20	increased	No data available	No data available	yes	No data available	No data	yes	Not done	none	No data available
phentermine	20	increased	elevated	Present	yes	yes	No data	yes	Not done	none	No data available
chlorphentermine	No comparative data	increased	elevated	present	Not reported	yes	No data	yes	Not done	6 instances	No data available
clortermine	No comparative data	No data	elevated	No data available	yes	yes	No data	yes	Not done	Not marketed	No data available
phenmetrazine	No comparative data	increased	elevated	present	yes	?	No data	No data	positive	yes	No data available
phendimetrazine	No comparative data	increased	elevated	present	Not reported	No data	No data	No data	Not done	none	No data available
fenfluramine	Mixed stimulant & depressant	decreased & increased	elevated	present	yes	yes	yes	yes	Negative	Depressant (Not marketed in U.S.)	No
mazindol	25	increased	not tod	Not observed	Detailed review unavailable	No	No data	yes	positive	Not marketed	yes
diethylpropion	10-20	increased	elevated	No data	yes	No	No data	yes	In progress	56 cases	No data avail.

while is a very rough estimate

Unpresumptive

205a

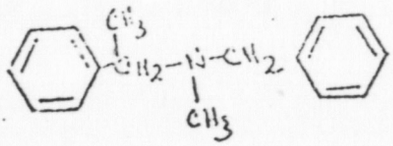
DRUG - TRADE NAME - CHEMICAL NAME & STRUCTURE	CNS PHARMACOLOGY
Phentermine - Phenyltertiary butylamine 	About 1/5 as stimulating in mice as d-amphetamine and about 1/3 as stimulating as d,l-amphetamine. Aggregate toxicity in mice but less than that for amphetamine. Anorexigenic in rats - given for 7 days about 1/2 as potent as amphetamine. About 1/3 as d,l-amphetamine on an acute basis in rats. No tolerance to anorexigenic effects in rats.
Clortermine - Voranil o-chloro, alpha, alpha, dimethylphenthylamine 	Suppressions of food reinforced behavior in monkeys.
Chlorphentermine - Pre-Sate p-chloro, alpha, alpha, dimethylphenthylamine 	CNS stimulation in rats and mice - d-amphetamine most potent; chlorphentermine least potent. CNS stimulation and toxicity in rats - 12 compounds compared - Dexedrine ranked first in potency and toxicity; chlorphentermine 9th, fenfluramine 12th. Rats - Acute administration produced weight loss but no increased motor activity. Failed to alter hexobarbital sleep time. Rats - d-amphetamine 10 times as potent as chlorphentermine in food motivated operant behavioral tests. Rabbits - 2.5 - 10 mg/kg IV produced EEG pattern compatible with sedation. Reduced or abolished arousal reaction produced by stimulation of the mesencephalic retricular activating. Rats prepared with chronically implanted electrodes in hypothalamus. Current necessary to elicit eating in these animals after they had been freely fed was measured. Chlorphentermine (also aleph. methamph, diethylprop; preludin) elevated current intensity necessary to elicit eating in dose related manner. Chlorphentermine given, IP, IV, or intracisternally to mice, rats, or rabbits produced a cataleptic response.

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DRUG - TRADE NAME - CHEMICAL NAME & STRUCTURE

CNS PHARMACOLOGY

Benzphetamine - Didrex - d-N-benzyl-N-alpha dimethylphenthylamine

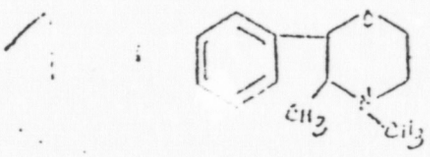


Dog studies	Benzphet.	Amphet.
Inhibition of food intake (acute	1	2 - 5
Inhibition of food intake (4 week study)	1	3
EEG acceleration	Transient	Prolonged
Reticular Activating System Antagonism of Phenobarbital EEG Pattern	Stimulated	Stimulated
	1	4
Subconvulsive Seizure Pattern	Absent	Absent
Pressor Effect	1	8
Tolerance Development	Present	Present

12 phenethylamine derivatives tested orally and IP in mice and rats. In terms of toxicity d-amphetamine first, benzphetamine eleventh, fenfluramine twelfth.

Overview - In anorexigenic tests in dogs, motor activity in mice and pressor effects in anesthetized dogs amphetamine was about 5 - 20 times as potent as benzphetamine, but qualitatively identical in terms of pharmacological profile.

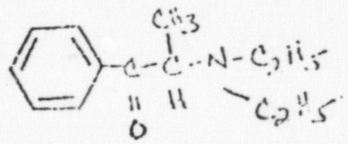
Phendimetrazine - Plegine 3,4-dimethyl-2-phenylmorpholine



Rat ED_{50} oral - 21 mg/kg. Similar to phenmetrazine (26 mg/kg) - Confirmed in rat actophotometry experiments less potent than diethylpropion. Anorexigenic activity in dogs - slight potency in voluntary broth consumption test in rats.

DRUG - TRADE NAME
CHEMICAL NAME & STRUCTURE

Diethylpropion - Tenuate, Tepanil
2-diethylaminopropiophenone



CNS PHARMACOLOGY

Potency Comparisons

Anorexia - 1/5 as potent as d-amphetamine in rats; 1/10 as potent as d-amphetamine in dogs.

Anorexia da CNS stimulation - ranked in order of potency - 7 agents tested, d-amphet. first, fenfluramine second; diethylpropion fourth, chlorphentermine 6th.

Dog - diamphetamine 1st, phentermine 3rd, fenfluramine 4th, diethylpropion 5th, chlorphentermin 6th.

Diethylpropion
MAO inhibition - weak

d-Amphetamine
MAO inhibition - 13 times as strong as diethylpropion.

Aggregate toxicity - Mice - None

Aggregate toxicity - ~~None~~ (present) Mice

Motor activity - Mice None

Motor Activity - Mice Increased

Fasted rats - Anorexia - acute study d-amphetamine - 4 times as potent.

CNS stimulation in rats, mice, rabbits - d-amphet. most potent and longest lasting diethylpropion and phenmetrazine - intermediate chlorphentermine - least potent.

Inhibition of voluntary beef broth consumption d-amphetamine, methamphetamine - most potent.

Diethylpropion, phendimetrazine, phenmetrazine - intermediate potency. l-amphetamine - active.

MAO Inhibitor Potency

Amphetamine 0.83
diethylpropion 1
tranylcypromine 6000

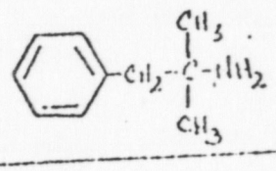
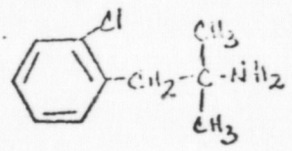
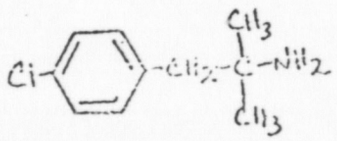
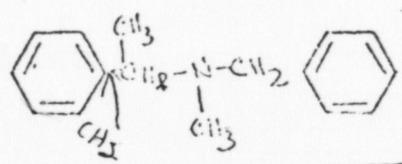
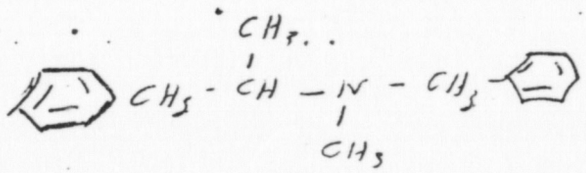
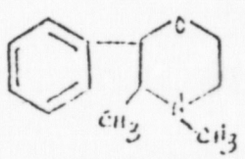
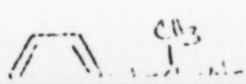
Motor Activity

Increased
Decreased
Decreased then Increased

Rats - Anorexigenic Effects

Potency

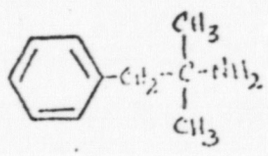
Diethylpropion = 1
Chlorphentermine = 2
Benzphetamine = 2
Phentermine = 2
d-amphetamine = 10

CHEMICAL NAME & STRUCTURE	CARDIOVASCULAR PHARMACOLOGY
Phentermine - Phenyltertiary butylamine 	Vasopressor effect equal to that of amphetamine and dependent on integrity of catecholamine stores in adrenergic neurons.
Clortermine - Voranil O-chloro, alpha, alpha, dimethylphenthylamine 	Anesthetized dogs - 1 mg/kg IV - pressor response 3 mg/kg - initial transient depressor response preceded by pressor 9 mg/kg - initial depressor response more severe followed by pressor response. This 9 mg/kg dose failed to alter responses to epinephrine, angiotensin II, bilaterial carotid occlusion or acctylicholine.
Chlorphentermine - Pre-Sate p-chloro, alpha, alpha, dimethylphenthylamine 	Chlorphentermine - 25 mg/kg/day for 5 days in rats for 5 days produced a blood pressure rise on Day 1 and 2 and a pronounced decrease from Day 3 on. Cardiovascular profile in dogs similar to d-amphetamine and diethylpropion. Did not potentiate pressor responses to norepinephrine (amphetamine and diethylpropion did).
Benzphetamine - Didrex - d-N-benzyl-N-alpha dimethylphenthylamine  	No data available.
Phendimetrazine - Plegine 3,4-dimethyl-2-phenylmorpholine 	Anesthetized dog -- no pressor effects at 1 and 4 mg/kg. Hypotension at 8 and 16 mg/kg. No EKG changes. Tachyphylaxis in rat blood pressure assay.
Diethylpropion - Tenuate, Tepanil 2-dithylaminopropiophenone 	Chloralose anesthetized dogs - 15 mg/kg produced slight pressor effects. Pressor - effects - Dog IV amphetamine - Greatest blood pressure rise.

DRUG - TRADE NAME
CHEMICAL NAME & STRUCTURE

210a TOXICOLOGY

Phentermine - Phenyltertiary butylamine



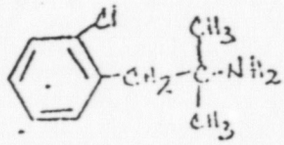
Resin Complex

Rat - up to 50 mg/kg/day for 6 months produced CNS stimulation and dose related weight gain depression. No tissue toxicity.

Tolerance to anorexigenic developed.

Dog - 5-15 mg/kg orally for 6 months. Dose related CNS stimulation, tachycardia weight loss. No tissue toxicity.

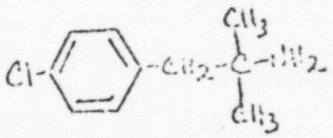
Clortermine - Voranil
O-chloro, alpha, alpha, dimethylphenthylamine



Rats - 200 mg/kg/day in diet for 1 year. Decreased weight gain and food consumption. No tissue toxicity.

Dog - 500 mg/kg for 1 year orally. Some decrease in weight gain for first 3 or 4 months. Some tolerance noted.

Chlorphentermine - Pre-Sate
p-chloro, alpha, alpha, dimethylphenthylamine

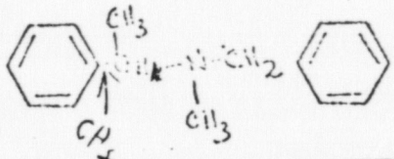


0, 10, 30, 60, 90 mg/kg via diet to rats for 18 mon.

Decreased weight gain and food consumption at 30 mg up. No tissue toxicity.

Dogs - 0, 5, 10, 20, mg/kg/day by capsule for 16 m No effect on behavior, growth rate, food consumptio or weight gain. No tissue toxicity.

Benzphetamine - Didrex -
d-N-benzyl-N-alpha dimethylphenthylamine

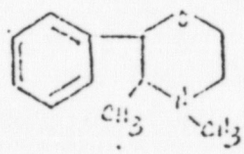


Rats - 0, 10, 30, 100 mg/kg/day orally for one year.

Dogs -0, 7.5, 15, 30 mg/kg/day for 6 months.

Weight gain depression without parallel decreases in food consumption. No tolerance reported to anorexigenic effects nor to CNS stimulant effects.

Phendimetrazine - Plegine
3,4-dimethyl-2-phenylmorpholine

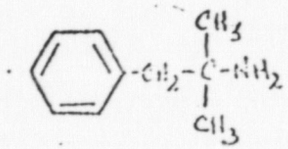
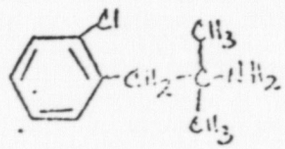
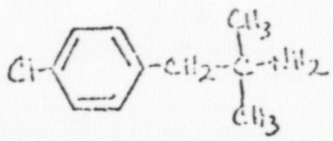
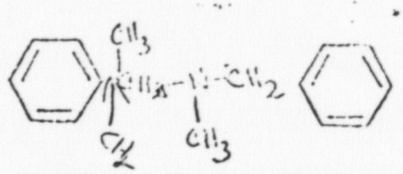
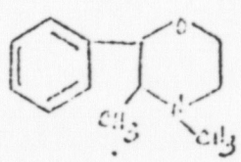


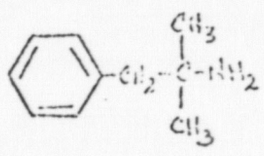
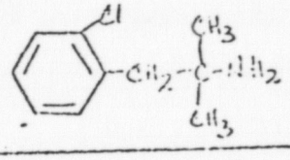
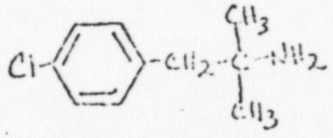
Rats receiving 20 - 90 mg/kg/day for 6.5 months. Dose related CNS stimulation. No tissue toxicity in dogs given 10 - 25 mg/kg/day for 6.5 months.

Diethylpropion - Tenuate, Tepanil
2-diethylamino propiophenone

Rats - 0.005% diet 145 days - No tissue toxicity. 0.01% via diet depressed weight gain but no tissue toxicity.

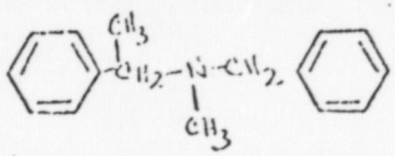
20 rats received 5 mg/kg IP for 21 months. No tissue toxicity

DRUG - TRADE NAME CHEMICAL NAME & STRUCTURE	BIOCHEMICAL DATA
Phentermine - Phenyltertiary butylamine 	Increased non-esterified fatty acid in blood of rats. Decreased blood glucose and increased plasma free fatty acids in dogs.
Clortermine - Voranil O-chloro, alpha, alpha, dimethylphenthylamine 	
Chlorphentermine - Pre-Sate p-chloro, alpha, alpha, dimethylphenthylamine 	Elevated plasma free fatty acids in the rat. O_2 consumption increased in anesthetized and non-anesthetized rats. d-amphetamine 10 time as potent. Brain, heart, fat and spleen norepinephrine levels were not altered by chlorphentermine in several animal species.
Benzphetamine - Didrex - d-N-benzyl-N-alpha dimethylphenthylamine 	NONE AVAILABLE.
Phendimetrazine - Plegine 3,4-dimethyl-2-phenylmorpholine 	Increased norepinephrine levels in rat brain. Failed to alter dopamine levels.
Diethylpropion - Tenuate, Tepanil 2-diethylamino propiophenone	Diethylpropion - 30 mg/kg IP failed to alter mouse Catecholamine levels. IP injection to rats of 5 mg/kg for 5 17 weeks decreased liver glycogen. No effect on body weight.

DRUG - TRADE NAME CHEMICAL NAME & STRUCTURE	METABOLISM STUDIES
Phentermine - Phenyltertiary butylamine 	NONE DONE
Clortermine - Voranil O-chloro, alpha, alpha, dimethylphenthylamine 	Man - Peak plasma levels after 5 hours. Plasma half-life about 9 hours. No metabolites were looked for.
Chlorphentermine - Pre-Sate p-chloro, alpha, alpha, dimethylphenthylamine 	Chlorphentermine given IV to rats; IM to rabbits & pigs. Highest levels in lung and spleen, adrenals, heart, kidneys and liver. Half-life in rats = 23 l. In man and dogs chlorphentermine excreted slowly in urine over 4-5 days (dogs) or 10 days (man). Drug not metabolized in rats chlorphentermine was found mainly in the adrenals, lung, kidneys, and s Rats - high levels of unchanged chlorphentermine i rats and prolonged retention time. No storage in adipose tissues. Rats excreted 70-80 of a given via urine as unchanged drug. Female mice excrete unchanged drug, 60 as an acidic conjugate and 15 an unknown metabolite. Hydrolysis of the conjugat yielded chlorphentermine.

Benzphetamine - Drinex
d N-benzyl-N-alpha
dimethylphenthylamine

213a

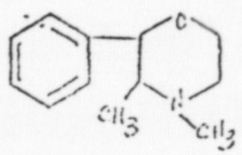


10 adult males - Single 75 mg dose or 5 - 15 mg doses at hourly inter . . Regardless of dosage schedule used about 80% of radioactivity recovered from urine and 3% from feces within one week after treatment. Tritiated water accounted for less than 1% of the total radioactivity.

Rats - Single 5 mg dose of H^3 or C^{14} radioactivity recovered within 48 hours.

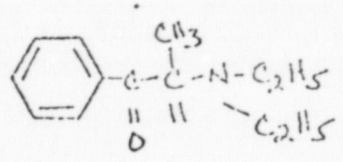
Dogs - Single dose of 5-8 mg/kg benzphetamine - C^{14} or H^3. Peak plasma levels observed 45 - 90 minutes treatment. About 95-99% of the radioactivity was recovered from urine and feces within 7 days aft treatment. Most of this radioactivity was recovered within 48 hours after treatment. Urine major excretory route.

Phendimetrazine - Plegine
3,4-dimethyl-2-phenylmorpholine



NO DATA AVAILABLE

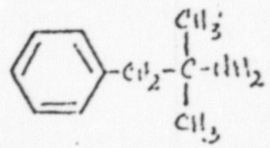
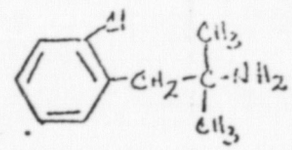
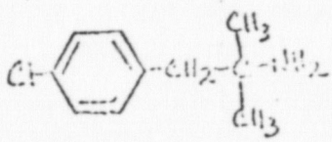
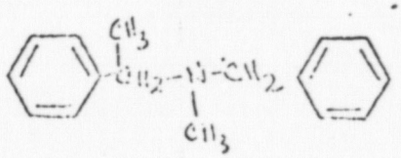
Diethylpropion - Tenuate, Tepanil
2-diethylaminopropiophenone



Man - Diethylpropion well absorbed from GI tract. Within 48 hours essentially all of the drug and drug related metabolites had been excreted. Half-life less than 8 hours.

Diethylpropion extensively metabolized by N-dealkyla tion, ring para-hydroxylation and oxidative cleavage of side chain. About 4-7.8% of the drug recovered from urine as unchanged drug.

About 16 metabolites in urine; none identified.

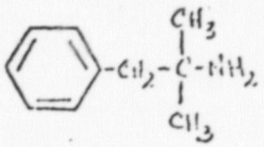
DRUG & TRADE NAME CHEMICAL NAME & STRUCTURE	CLINICAL DATA : Abuse
Phentermine - Phenyltertiary butylamine 	Major side effects - Insomnia and nervous irritabil One report of mood elevation comparable to those o the amphetamines.
Clortermine - Voranil O-chloro, alpha, alpha, dimethylphenthylamine 	
Chlorphentermine - Pre-Sate p-chloro, alpha, alpha, dimethylphenthylamine 	In various psychological tests, chlorphentermine a d-amphetamine similar effects. Chlorphentermine w longer lasting. Normal males - EEG alpha, blocking response to pho stimulation was not blocked. Chlorphentermine was about equivalent to d-amphet as an anorexigenic agent over 16 weeks in 29 obese patients.
Benzphetamine - Didrex - d-N-benzyl-N-alpha dimethylphenthylamine 	EEG patterns in human volunteers with benzphet., diethylpropion and phentermine. All three drugs showed similar EEG patterns with benzphetamine showing the lowest incidence of EEG alterations. Benzphetamine produced less CNS stimulation than did amphetamine. Double-blind placebo - controlled in 50 obese prisoners - Mood elevation a side effec Difficulty in getting to sleep; dose related incid 6/24 subjects treated with benzphet. reported mood elevation. Only 1 of 24 on placebo showed this. 13/21 patients taking 150 mg/day of benzphetamine for 20 weeks reported an exhilarating effect. 5 reported dreams and pseudohallucinations.
Phendimetrazine - Plegine 3,4-dimethyl-2-phenylmorpholine	
Diethylpropion - Tenuate, Tepanil 2-diethylaminopropiophenone 	CNS stimulation with phenmetrazine was greater than with diethylpropion. No "lift" produced. No lete after drug was stopped.

DRUG - TRADE NAME
CHEMICAL NAME & STRUCTURE

EUPHORIA

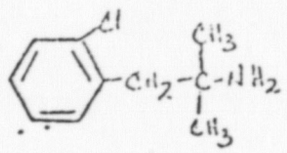
Phentermine - Phenyltertiary butylamine

Mood elevation in a few patients.



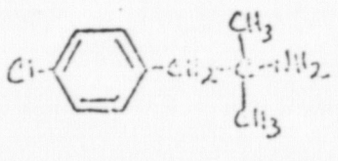
Clortermine - Voranil
O-chloro, alpha, alpha, dimethylphenethylamine

Two instances reported.

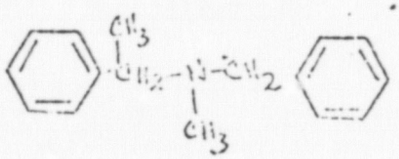


Chlorphentermine - Pre-Sate
p-chloro, alpha, alpha, dimethylphenthylamine

No stimulation and elevated mood states such as self-assertiveness involvement with surroundings and happenings.

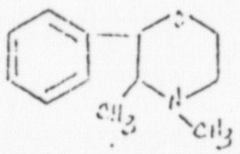


Benzphetamine - Didrex -
d-N-benzyl-N-alpha dimethylphenthylamine

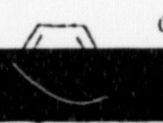


Phendimetrazine - Plegine
3,4-dimethyl-2-phenylmorpholine

Observed in a few patients.

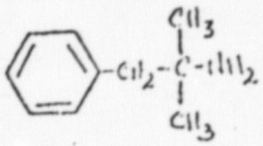


Diethylpropion - Tenuate,
Tepanil
2-dithylaminopropiophenone



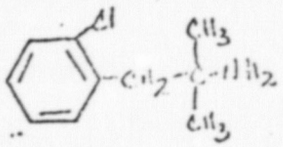
Phentermine - Alkylated tertiary butylamine

None



Clortermine - Voranil
U-chloro, alpha, alpha, dimethylphenthylamine

Drug not yet marketed nor tested overseas

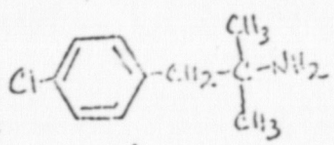


Chlorphentermine - Pre-Sate
p-chloro, alpha, alpha, dimethylphenthylamine

Chlorphentermine failed to substitute for morphine in morphine.

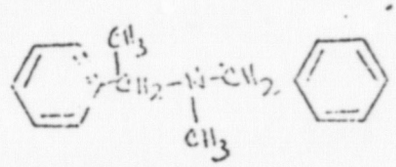
An emotionally unstable and immature girl who had previously taken d-amphetamine and Preludin took up to 10 tablets per day on and off for 9 months She got a "lift" from it "though much less" than d-amphetamine and phenmetrazine.

Two cases from Denmark No details One case where chlorphentermine was used as a narcotic. One overweight psychiatric patient had to be readmitted to the hospital despite satisfactory weight loss (5kg in 3 months) and treatment had to be discontinued by nursing staff.



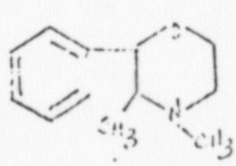
Benzphetamine - Didrex -
N-benzyl-N-alpha
dimethylphenthylamine

Not available



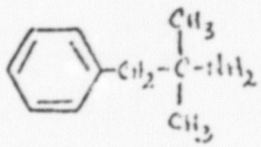
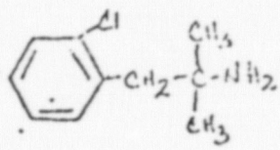
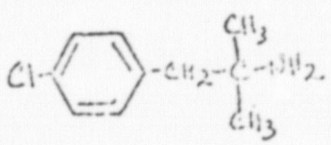
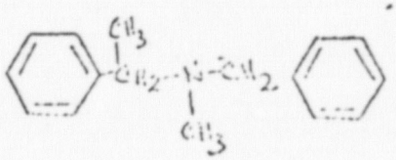
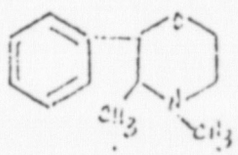
Phendimetrazine - Plegine
3,4-dimethyl-2-phenylmorpholine

None



Diethylpropion - Tenuate,
Tepanil
2-diethylaminopropiophenone

96 cases - U.S., United Kingdom, Germany, Holland, Sweden. Vast majority were females. Age range (where stated) - 15-67. Previous Drug Abuse - Mainly amphetamine and phenmetrazine. Duration of Abuse - 2 weeks to 11 years. Maximum Daily Dose 75 to 750mg.

DRUG - TRADE NAME CHEMICAL NAME & STRUCTURE	MONKEY SELF-ADMINISTRATION
Phentermine - Phenyltertiary butylamine 	Not done
Clortermine - Voranil O-chloro, alpha, alpha, diethylphenthylamine 	Not done
Chlorphentermine - Pre-Sate p-chloro, alpha, alpha, diethylphenthylamine 	No reinforcement of self-administration behavior.
Benzphetamine - Didrex - d-N-benzyl-N-alpha diethylphenthylamine 	Not done.
Phendimetrazine - Plegine 4-diethyl-2-phenylmorpholine 	Not done
Diethylpropion - Tenuate, Tepanil 2-diethylaminopropiophenone 	In progress

BENZPHETAMINE-DIDREX - d-N-benzyl-N, alpha dimethylphenethylamine

LD_{50} (limits) mg/kg	Comparative Potency of Benzphetamine[1,3] Pharmacology		Toxicology[1]	Clinical Data[1]	Metabolism Studies[1]	Human Abuse Evidence	Monkey Self-Administration	FDA Checked
	Dog Studies	Benzphet. Amphet.						
Mice IP Isolated: 123 (115-131) Grouped: 102 (93-111)	Inhibition of food intake (acute)	1 2-5	Rats - 0,10,30, 100 mg/kg/day orally for one year. Dogs - 0,7.5,15,30 mg/kg/day for 6 months Weight gain depression without parallel decrease in food consumption. No tolerance reported to anorexigenic effects nor to CNS stimulant effects.	EEG pattern patterns in human volunteers receiving benzphetamine, diethylpropion and phentermine. All three drugs showed similar EEG patterns with benzphetamine showing the lowest incidence of EEG alterations. Benzphetamine produced less CNS stimulation than did amphetamine. Double-blind placebo controlled study in 50 obese prisoners - Mood elevation, a side effect. Dose related frequency in getting to sleep at night. In a later study - 6/24 subjects treated with benzphetamine reported mood elevation compared to 1/24 subjects on placebo. 13/21 patients taking 150 mg/day of benzphetamine for 30 weeks reported an exhilarating effect; medication made their minds clearer, could concentrate better and seemed to have better retentive powers. Several of the group were professionals and used the drug as a stimulant and a "wake-upper" noting that it did not have the nervous, jittery effect of d-amphetamine. In 5 patients dream production and pseudo-hallucinations similar to those produced by mescaline. Dreams were bizarre, fanciful, and in some instances, erotic but very realistic. The patients had difficulty in remembering the exact details of the dreams. The dreams were pleasant, delightful and took them "out of this world"; no after effects such as lassitude.	10 adult males receiving a single 75 mg or five 15 mg at hourly intervals. Regardless of dosage schedule used about 80% of radioactivity recovered from urine and 3% from feces within 1 week after treatment. T Tritiated water accounted for less than 1% of the total radioactivity. Rats - Single 5 mg dose of H^3 or C^{14} or H^3 radioactivity recovered within the first 48 hours. Dogs - Single dose of 5-8 mg/kg benzphetamine - C^{14} or H^3. Peak plasma levels observed 15-90 minutes post-treatment. About 95-99% of the radioactivity was recovered from urine and feces within 7 days after treatment. Most of this radioactivity was recovered within 48 hours after treatment. Urine major excretory route.	NONE	NOT DONE	YES
	EEG acceleration	Transient Prolonged						
	Reticular Activating System Antagonism of Phenobarbital	Stimulated Stimulated						
	EEG Pattern	1 4						
	Subconvulsive Seizure Pattern	Absent Absent						
	Pressor Effect	1 8						
	Tolerance Development	Present Present						
	12 phenethylamine derivatives tested orally and IP in mice and rats. In terms of toxicity d-amphetamine ranked first, benzphetamine eleventh, fenfluramine twelfth.[2]							
	Overview - In anorexigenic tests in dogs, motor activity in mice and pressor effects in anesthetized dogs amphetamine was about 5-20 times as potent as benzphetamine, but qualitatively identical in terms of pharmacologic profile.							

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BIBLIOGRAPHY

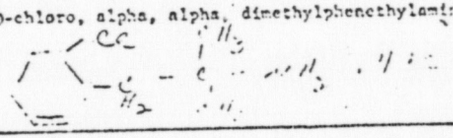
BENZPHETAMINE

1. NDA 12-427

2. Boissier, J.R. Therapie 20(2), 297-309, 1965.

3. Veldkamp, W. et al. Toxicol. Appl. Pharmacol. 6(1), 15-22, 1964.

Clortermine - Voranil O-chloro, alpha, alpha, dimethylphenethylamine



mg/kg	CNS Pharmacology	Cardiovascular Effects	Biochemical Effects	Toxicology	Euphoria	Information re Abuse	Self Administration Technique - Monkeys	NDA Examined	Metabolism Study
- Juvenile Oral 434.70 ± 75 - Adult IV 21 - Adult Oral 333 - Adult IV 21 ± 2.87 - Adult Oral 332 ± 23 e IV 19 ± 1 e Oral 322 ± 45 IV 21 ± 2 Oral 332 ± 23 IV less than 50 Oral exceeds 100	Self session of food reinforced behavior in monkeys	Anesthetized Dogs - 1mg/kg IV - pressor response 3mg/kg - initial transient depressor response preceded pressor effect. 9mg/kg - initial depressor response more severe, followed by pressor response. This 9mg/kg dose failed to alter responses to epinephrine, angiotensin II, bilateral carotid occlusion, or acetylcholine	Single oral 10mg/kg dose in glucose loaded rats failed to affect blood glucose	Except for decreased body weight gain and food consumption rats could tolerate 200mg/kg per day mixed in the diet for one year with no adverse effects upon the usual toxicology parameters. Dogs could tolerate upto 50mg/kg/day except for some decrease in body weight for the first three or four months of the study reflecting probably some degree of tolerence	2 instances where this has been reported as a side effect	Drug not yet marketed Drug has not been tested over seas. None	Not Done	No	Man - Peak plasma levels after 5 hours. Plasma half life about 9 hours. No metabolites were looked for

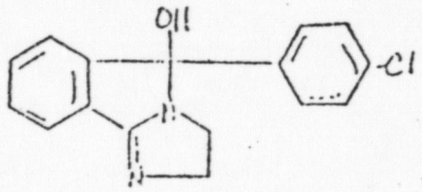
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Bibliography - None

All data taken from NDA 16-880

dihydro-5H-imidazo(2,1a) isoindole



Potency

Mazindol = 1
Methamphetamine = 4
d-amphetamine = 9
chlorphentermine = 0.4
diethylpropion = 0.4

Longer acting than d-amphetamine; like d-amphetamine tolerance to anorexgenic effect was observed.

Muricidal behavior in septal lesioned rats - This is abolished by mazindol, as well as chlorphentermine and methamphetamines.

Stereotyped behavior in rats produced by mazindol as well as amphetamine. Effect blocked by alpha methyldopa and enhanced by amitriptyline and imipramine.

Variable Ratio Food Schedule - Monkeys - response rate suppressed.

Potency

Mazidol = 1
d-amphetamine = 4
methamphetamine = 4
chlorphentermine = 0.13
diethylpropion = 0.13

Same experiment in Capuchin Monkeys

Potency

Mazindol = 1
d-amphetamine = 1
Chlorphentermine = 0.25
diethylpropion = 0.16
fenfluramine = less than 0.13

Mazindol had delayed onset of action and produced less CNS stimulation.

Muricideal Behavior - Rats (non-lesioned)

Potency

Mazindol = 1
Methamphetamine = 1.5
d-amphetamine = 1.5
Chlorphentermine = 0.75
Imipramine = 0.? oral 0.25 IP

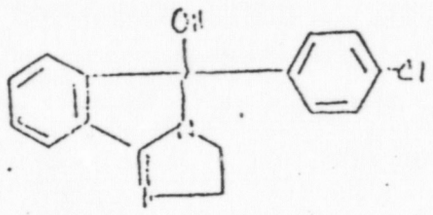
EEG Cat - arousal, enhanced septal-induced lesions - different from CNS stimulants.

Evoked potentials - Cat - Data indicate part of CNS activity of mazindol mediated in septal area of brain. Methamphetamine produced non-specific excitation.

Aggregate toxicity in mice observed. Effect less marked in comparison to amphetamine.

Produced increased activity in mice, d-amphetamine more potent. Similar results in rats. Duration of onset, delayed and shorter than d-amphetamine. Tolerance seen in rats on acute basis but not on a 5 day schedule.

Mazindol - Sanorex
5(4-chlorophenyl)-5-hydroxy-2,3-dihydro-5H-imidazo(2,1a) isoindole



Dopa potentiation in mice - more potent than amitriptyline

Reserpine hypothermia in mice - Blocked by mazindol; 25 times as potent as imipramine.

No effect on body temperature in normothermic mice.

Tetrabenazine reversal - Rats

Mazindol 40 times as potent as amitriptyline

Sidman avoidance - Rats - CNS stimulation; amphetamine 20 times as potent.

Cats - Sidman avoidance - CNS stimulation produced shorter duration than d-amphetamine

Squirrel Monkeys - Sidman avoidance - food getting behavior reduced at doses that produced no CNS stimulant activity.

Analgesic activity in mice (hot plate) and rats (Randall Selitto) reduced hexobarb-sleeping time in mice.

No ataxia in mice (rotarod)

Antagonized oxotremorine in mice.

CARDIOVASCULAR PHARMACOLOGY

Anesthetized dog - Dose related hypotension
Responses to norepinephrine potentiated
Angiotensin potentiated; dose related inhibition of tyramine.

Responses to acetylcholine unaltered.

No effects on pulmonary artery pressure, pulmonary pressure, pulmonary resistance.

Above effects seen when mazindol was given intraduodenally to anesthetized dogs.

Vagotomized dogs - Dose related potentiation of norepinephrine hypertension.

Unanesthetized dogs - No effect on blood pressure 1 mg/kg.

Norepinephrine responses potentiated.

Unanesthetized rats - No blood pressure changes a 24 mg/kg orally. No changes in heart rate or bel

No alterations in heart rate in conscious monkeys.

In anesthetized dogs - potentiated pressor respo to 5 HT.

Mazindol - Sanorex
5(4-chlorophenyl)-5-hydroxy-2,3-dihydro-5H-imidazo(2,1a) isoindole

No effect on plasma free fatty acids in rats d-amphetamine elevated these.

No effect on blood glucose in chicks or fasted ra

Reduced serum triglycerides in rats but had no effect on serum cholesterol.

Moderate reduction in active transport of glucose in rats; palmitate unaffected.

No effect in charcoal meal test in rats.

EFFECT ON NEUROHUMORS

Moderate decrease in brain 5HT in mice (not dose-related).

No effect on catecholamines.

Methamphetamine - Increased brain catecholamine levels; no effect on 5HT.

MAO and catechol-O-methyl transfera e not affecte

Rats - decreased H^3 and H^3 - norepinephrine and no significant effect on metanephrine. Inhibits u uptake and release of norepinephrine in brain tiss

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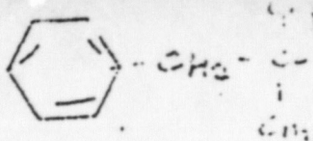
SELF-ADMINISTRATION - MONKEY

Schuster

Unit dosages - 50 or 100 mcg/kg maintained self-administration behavior at higher frequency. At 200 mcg/kg behavior was not significantly differen from saline.

Daily drug intake very stable which also occurs with other CNS stimulants self-administered by the rhesus monkey.

PHENTERMINE - IONAMIN - phenyl tertiary butylamine
dimethylphenylethylamine



LD50 mg/kg	CNS Stimulant Activity	Cardiovascular Effects	Toxicology
Oral-Rat 155 (120-190) Oral-Mice 124 (109-140) as HCl Salt	About 1/5 as stimulating in mice as d-amphetamine and about 1/3 as stimulating as d l-amphetamine. Resin complex more potent in rats.	Dog-Vasopressor effect equal to that of amphetamine. Potentiated pressor response to tyramine in the dog; amphetamine did not. 2	Resin Complex Rat - up to 50mg/kg/day for 6 months produced CNS stimulation and dose related weight gain depression. No tissue toxicity. Tolerance to anorexigenic effect developed. Max.tolerated dose 30-40 mg kg estimated Dog - 5-15mg/kg orally for 6 months. Dose related CNS stimulation tachycardia, weight loss. No tissue toxicity. Max. tolerated dose - 15 mg kg approx. Less toxic in grouped mice than amphetamine.
Oral-Rat 450(216-686) Resin Complex	Aggregate toxicity in mice but less potent than amphetamine. As anorexigenic about 1/2 as potent as d,l-amphetamine when administered to rats for 7 days. About 1/3 as potent as d,l-amphetamine as anorexigenic on acute basis in rats. Similar in potency to amphetamine as anorexigenic. Anorexigenic effects more pronounced in isolated rats. No interaction with amphetamine. No tolerance to anorexigenic effects in rats. 7	Vasopressor activity depends upon integrity of catecholamine stores in adrenergic neurones. 3 10^{-7} M-phentermine produced contractions in isolated cat papillary muscles. 4 Similar to amphetamine - Rats receiving 11 mg/kg/day for 5 days orally showed elevated blood pressure. 5	

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Biochemical Data	Clinical Data re: Abuse [9]	Euphoria [9]	Abuse Information	Monkey - Self-Administration	NDA Examined
Increased non-esterified fatty acids in blood of rats. [6,5] Decreased blood glucose and increased plasma free fatty acids in dogs.	Major side effects — Insomnia & nervous irritability. One report of mood elevation comparable to those of the amphetamines. Phentermine & d-amphetermine prepared in a resin complex lost their anorectic effect in 6-8 weeks. Phentermine produced minor CNS stimulation. This was more pronounced with d-amphetamine.	Mood elevation noted in a few patients.	None.	Not done.	YES.

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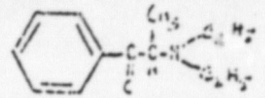
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FDH - Sour

Diethylpropion - Tenuate, Tepanil 2-diethylaminopropiophenone



Acute Toxicity LD_{50} (limits) mg/kg	CNS Pharmacology	Cardiovascular Studies	Toxicology
Mice IV - 100 SC - 200 Oral- 800	Potency Comparisons Anorexia - 1/5 as potent as d-amphetamine in rats; 1/10 as potent as d-amphetamine in dogs.[2]	Dogs anesthetized with chloralose - 15 mg/kg produced slight blood pressure elevations.	Diethylpropion given to rats in diet at 0.05% for 1'd days - no tissue toxicity. 0.01% via diet over 170 days depressed weight gain but no hematologic nor pathologic changes
Mice - Oral 225 (220-230 - 1/5 as toxic as d-amphetamine	Anorexia and CNS stimulation - Ranked in order of potency. Rat - 7 agents tested. d-amphetamine first; fenfluramine second; diethylpropion 4th, chlorphentermine 5th. Dog - d-amphetamine first, phentermine third; fenfluramine 4th, diethylpropion 5th, chlorphentermine 6th.[5]	Vasoconstrictive effects in the perfused rabbit ear - 5-20 mg/kg in rats increased diuresis 100-200% for one hour.[21]	20 rats received 5 mg/kg IP for 11 months. No tissue toxicity.[1]
Rat - Oral 200 (177-299) 1/15 as toxic as amphetamine.[2]		Isolated frong-heart - 10^{-4M} phentermine and diethylpropion - ineffective; d-amphetamine decreased contraction amplitude and stopped the heart. 10^{-5} - d-amphetamine still effective. When heart stopped washing to Ringer's solution made heart start again. None of the drugs affected heart rate.	6 beagles dogs received 10 mg/kg/day orally for 6 months. No tissue nor organ toxicity. Slight increase in body weight gain in test animals.
Mice - IP 167+10 Oral 385+61	Diethylpropion MAO inhibition - weak Aggregate toxicity - Mice - None Motor activity - mice No increase	d-Amphetamine MAO inhibition 12 times as potent as diethylpropion Aggregate toxicity Mice - Present Motor activity - mice - increased	Rats - 3 months - 0,10,50,100 mg/kg. Slight weight gain depression in high dose rats. Hematuria, and gross and histopathology were unremarkable.[4]
Rats-IP 312+24 Oral- 405+20[3]			
Mice - IP exceeds 100 Oral exceeds 200	Rat - rope climbing test - No CNS stimulation.	Isolated perfused guinea pig heart 10^{-3}% for all three drugs was toxic. 10^{-4}% of d-amphetamine decreased amplitude of contraction, the other two were ineffective. 10^{-5}M-d-amphetamine produced decreased effect. 10^{-6}% was ineffective. Washing with Ringer's solution restored normal contractibility.[22]	Histological examination of dogs and rats were treated with diethylpropion over a 6 month period. Dogs receiving 10 mg/kg orally and rats 100 mg/kg orally failed to reveal any tissue defects or disturbances. No area of necrosis were found in the heart wall.[20]
Rat IV - approx. 50 Oral- approx. 250	Rat rope climbing test - CNS stimulation.		
Dog IV - 50-100 Oral- 125-250	Interaction with meprobamate - None Fasted rats - diethylpropion orally or IP on acute basis depressed appetite. About 1/4 as potent as d-amphetamine Diethylpropion showed CNS stimulant effect.[7]	Pressor effects - Dog IV amphetamine - Greatest blood pressure rise.	
	Interaction with meprobamate - Antagonism[6]		

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CNS Pharmacology (continued)

Mice, rats, rabbits - CNS stimulation

d-amphetamine most potent and longest lasting diethylpropion and phenmetrazine - intermediate in potency.

Chlorphentermine - least potent.[11]

Inhibition of voluntary beef broth consumption - Rats
d-amphetamine, metamphetamine - most potent inhibitors.

Diethylpropion, phenmetrazine, phendimetrazine - intermediate potency.

l-amphetamine - inactive.[12]

	MAO Inhibitor Potency	Motor Activity
amphetamine	0.33	Increased
diethylpropion	1	Decreased
tranylcypromine	6000	Decreased then increased

Miscellaneous Studies

Cold intolerance tests mice showed no weight loss nor reduction in food consumption after diethylpropion treatment. The opposite was seen in non-acute mice.[13] d-amphetamine and phenmetrazine were ineffective in both groups of mice. Benzphetamine was ineffective.

In rats desmethylimipiame caused marked potentiation and prolongation of the anorectic and CNS stimulating effect of d-amphetamine, phentermine, and diethylpropion but not of phenmetrazine and chlorphentermine.[15]

Behavioral Study - Rats - 2.5 and 10 mg/kg diethylpropion SC - No effect.[16]

Diethylpropion, amphetamine (and many other drugs) reversed reserpine-induced hypothermia in mice.[17]

Rats - 5 mg/kg IP decreased activity, 15 mg/kg. IP increased activity, 30-35 mg/kg increased activity in mice. 5-10 mg/kg failed to alter hexobarbital sleeping time in mice. Higher doses (20-40 mg/kg) prolonged sleeping time.[18]

Diethylpropion, phenmetrazine and dl-amphetamine given SC to mice and rabbits IV to dogs. In doses of 5-40 mg/kg all compounds increased motor activity; diphenylpropion and phenmetrazine produced less CNS stimulation. Metrazol convulsions potentiated by all 3 drugs; diethylpropion less potent. All 3 drugs produce hyperthermia. Diethylpropion was less effective in reversing reserpine sedation than phenmetrazine or dl-amphetamine. Neither diethylpropion nor phenmetrazine effected hexobarbital or other narcosis.[19]

Rats - Stereotyped behavior produced by amphetamine, methamphetamine, phenmetrazine, diethylpropion, methylphenidate and pipradol. This consisted of sniffing, licking, and biting and rage reaction characterized vocalization and fighting. Rage produced by injection of MAO inhibitors followed by dopa or imipramine. The stereotyped hyperactive behavior associated with dopamine levels in the corpus striatum. This reaction can be produced by microinjection of dopamine and anticholinergics into the corpus striatum. Perphenazine and CPZ prevent this behavior. Norepinephrine implicated in the reaction.[20]

In mice diethylpropion did not reverse reserpine depression.[29]

Rats - Anorexigenic effect

Potency

Diethylpropion = 1
Chlorphentermine = 2
Benzphetamine = 5
Phentermine = 2
d-amphetamine = 10[30]

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Effect on Neurohumors	Biochemical Studies	Human Metabolism Data	Clinical Data re Abuse Potential	Monkey Self-Administration Test	NDA Tested at
Diethylpropion - 30 mg/kg IP failed to alter mouse brain catecholamine levels[27] CATECHOLAMINE	IP injections to rats of 5-30 mg/kg for 5-17 weeks decreased liver glycogen. Body weight not affected.[28] Diethylpropion decreased weight of rat epididymal fat pad.[30] Potency as MAO Inhibitors Diethylpropion = 1 Phendimetrazine = 3 Methamphetamine = 10[31] Phenmetrazine = No values reported Lipid mobilization from rat adipose tissues *in vitro*. Amphetamine, methamphetamine. Marked lipid mobilization. Phenmetrazine - slight activity. Chlorphentermine, diethylpropion - No activity.[32]	Diethylpropion well absorbed from GI tract. Within 48 hours essentially all of the drug and drug related metabolites regardless of IV or oral administration. Total radioactivity studies showed half life of less than 8 hours.[33] Diethylpropion extensively metabolized by N-dealkylation, para-hydroxylation of the ring and oxidative cleavage of the chain. About 4-7.8% of the dose recovered from urine as unchanged drug. About 16 metabolites in urine. None identified.[34]	CNS stimulation with phenmetrazine was greater than with diethylpropion.[35] Diethylpropion failed to produce the "lift" experienced after injection of amphetamine.[36] No letdown after drug was discontinued. No mood elevation.	In progress	NO

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PUBLISHED AND UNPUBLISHED REPORTS OF DIETHYLPROPION ABUSE

SOURCE	SEX	AGE	PREVIOUS DRUG ABUSE	PRE-EXISTING PSYCHIATRIC DIAGNOSIS	OCCURRENCE OF PSYCHOSIS	DURATION OF ABUSE	MAXIMUM DAILY DOSE (mg) TOTAL
Temple-Wanka[37]	F	24	Phenmetrazine	None	yes	not stated	110
Temple-Wanka[37] 6 cases with no discrete data	F	18	Phenmetrazine	None	None	2 years	2,500
Clein[38]	F	Not Stated	Amphetamine Phenmetrazine	Immature Personality	None	Not Stated	Not Stated
Kuesbert[39]	F F	32 30	None Amphetamine	None None	yes yes.	3 months Not Stated	75 300
Clein & Benady[40]	F	26	Amphetamine Phenmetrazine	Inadequate personality	yes	2 years	2,250
Caplan[41]	F	27	Phenmetrazine Amphetamine	Personality disorder	None	9 months	7,500
Merrell Internal Report[37]	F	23	None	Paranoid Personality	Yes	6 months	600
Merrell Internal Report[37]	F	40	Amphetamine Alcohol Barbiturates	Schizophrenia	None	More than 2	375
Merrell Internal Report[37]	F	24	Amphetamines	None	None	18 months	750
Merrell Internal Report[37]	F	37	None	None	None	Not Stated	300
Curling[42]	F	67	Phenmetrazine	None	None	1 Year	750
Bauman[43]	F	42	None	None	Yes (paranoid delusions)	6 months	375

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SOURCE	SEX	AGE	PREVIOUS DRUG ABUSE	PRE-EXISTING PSYCHIATRIC DIAGNOSIS	OCCURRENCE OF PSYCHOSIS	DURATION OF ABUSE	MAXIMUM DAILY DOSE (mg/day)
Murrell, Internal Report 87	F	32	None	Schizophrenia	None	6 months	300
Darling 82	F	67	Phermetrazine	None	None	1 year	750
Bourne 83	F	42	None	None	Yes (Paranoid delusions)	6 months	375
Murrell, Internal Report 87	F	32	None	Schizophrenia	None	6 months	300
Dunston 84	F	18	None	Immature Personality.	Yes	6 months	150
Murrell Internal Report 87	Two out of 50 patients at an addiction clinic abused diethylpropion. No details given.						
Jones	F	Not Stated	Phermetrazine Amphetamine	Immature, Hysterical Phobic Personality	Yes	Not stated	Not Stated
Murrell Internal Report 87	F	Not Stated	Amphetamine	None	Yes	6.5 years	150

PUBLISHED AND UNPUBLISHED REPORTS OF DIETHYLPROPION ABUSE (CONT.)

Source	Sex	Age	Previous Drug Abuse	Pre-existing Psychiatric Diagnosis	Occurrence of Psychosis	Duration of Abuse	Maximum Daily Dose (mg) Total
Allmark and Rylander 46	7 M	19-23	Marihuana, Alcohol	none	2.7	1 year	625
Rylander 45	M	not stated	Phenmetrazine methylphenidate	none	none	not stated	625
Bergman and Jarpe - Mathiesen 47	F 3 M 3 not stated	not stated not stated not stated	Experience from Karolinska Addiction Clinic in 1963, 1965 and 1967. Few Details given.				not stated
Merrell Internal Report 37	F	57	Amphetamine	none	none	6 months	1200
Dejerat 43	M	not stated	none	none	yes	not stated	not stated
Whitlock and Nadorff 49	F	26	Amphetamine	Hysterical Personality	yes	1 year	75+
Merrell Internal Report 37	M	30	Amphetamine Methylphenidate	none	none	not stated	100-300
Merrell Internal Report 37	F	41	none	none	yes	4 years	75
Merrell Internal Report 37	F	27	none	Schizophrenia (?)	yes	6 years +	2250
Punto 37	Seven cases reported from abuse clinics out of 400 patients. Details not yet available. Merrell waiting for information.						
Dachs 37	Merrell awaiting data.						

Source	Sex	Age	Previous Drug Abuse	Pre-existing Psychiatric Diagnosis	Occurrence of Psychosis	Duration of Abuse	Maximum Daily Dose (mg) Total
Merrell Internal Report 37	M	24	Amphetamine Phenmethrazine	Schizophrenia	yes	4 years	900
Merrell Internal Report 37	F	26	Darvon	not stated	not stated	4 months	525
Merrell Internal Report 37	M	47	Amphetamine	Narcolepsy	no	not stated	not stated
Merrell Internal Report 37	M	60	Darvon, Meprobamate Diazepam	Possible Paranoid Delusions	no	not stated	not stated

PUBLISHED AND UNPUBLISHED REPORTS OF DIETHYLPROPION ABUSE (Cont)

Source	Sex	Age	Previous Drug Abuse	Pre-Existing Psychiatric Diagnosis	Occurrence of Psychosis	Duration of Abuse	Maximum Daily Dose (mg) Total
Merrell-37	F	Middle-aged	Amphetamine Methylphenidate	not stated	not stated	not stated	not stated
Merrell Internal Report37	F	36	Amphetamine	Immature Personality Compulsive eater	no	6 months	75
Merrell Internal Report37	F	22	Schizoid Personality	No	None	14 days	75
Merrell Internal Report37	2 or 3 students at Oregon State University, alleged to have taken Tenuate Dospan to help keep awake while studying during 1969 - 1970						
Merrell Internal Report37	F	29	Methylphenidate	Narcolepsy?	No	less than 10 months	375
Merrell Internal Report37	M	15	not stated	not stated	not stated	not stated	not stated but used IV
Merrell Internal Report37	No detailed information (Yarrowonga, Victoria)						
Merrell Internal Report37	No detailed information (New South Wales, Australia)						
Merrell Internal Report37 Data in Appendix 38	M	Teenager	not stated	not stated	not stated	not stated	1350
Merrell Internal Report37	F	50+	Amphetamine	None	Acute Depression 1966	6 years	Probably more than 75
Merrell Internal Report37	F	47	Amphetamine	Unstable Personality Low IQ	No	2 years	150
Merrell Internal Report37	F	46	Amphetamine	none	no	21 months	75
Merrell Internal Report37	F	50	not stated	not stated	not stated	3 years	75
Merrell Internal Report37	F	41	Amphetamine	Post-influenzal depression	No	11 years	225

PUBLISHED AND UNPUBLISHED REPORTS OF DIETHYLPROPION ABUSE (CONT)

Source	Sex	Age	Previous Drug Abuse	Pre-Existing Psychiatric Diagnosis	Occurrence of Psychosis	Duration of Abuse	Maximum Daily Dose (mg) Total
Merrell Internal Report 37	F	Middle-aged	Not stated	Not stated	Not stated	Not stated	Not stated
Merrell Internal Report 37	F	Not stated	Not stated	Not stated	Not stated	Not stated	350
Merrell Internal Report 37	F	52	Amphetamines	Inadequate Personality	No	15 months	225
Merrell Internal Report 37	F	45	None	Anxiety Neurosis	No	3 years +	150
Merrell Internal Report 37	F	50	None	None	3 days	Not stated	150
Merrell Internal Report 37	F	31	None	Depression Immature Personality	None	5 -66 years	750
Merrell Internal Report 37	F	30 +	Not stated	Not stated	Not stated	Not stated	750
Merrell Internal Report 37	F	Not stated	Not stated	Not stated	Not stated	2 - 3 years	75
Merrell Internal Report 37	F	Not stated	Not stated	Not stated	Not stated	Not stated	300
	F	Not stated	Not stated	Not stated	Not stated	Not stated	7225
Merrell Internal Report 37	F	57	None	Anxiety, Nervous Reaction, Depression	No	3 years 8 months	225
Merrell Internal Report 37	F	48	Not stated	Not stated	Not stated	6 - 8 years	150
Merrell Internal Report 37	F	46	Not stated	Inadequate Personality	No	About 1 year	75
Merrell Internal Report 37	F	17	None	Anxiety	Reactive depression Paranoid features after Tenuate withdrawal	3 years +	225

Published and Unpublished Reports of Diethylpropion Abuse (CONT)

Source	Sex	Age	Previous Drug Abuse	Pre-Existing Psychiatric Diagnosis	Occurrence of Psychosis	Duration of Abuse	Maximum Daily Dose (mg) Total
Merrell Internal Report 37	M	Young	Not stated	Not stated	Not stated	Not stated	75?
Merrell Internal Report 37	F	49	No	Mild depression	No	7 Years approximately	75
Merrell Internal Report 37	F	Young	Not stated	Unstable	Not stated	Not stated	Not stated
Merrell Internal Report 37	F	40	Not stated	Not stated	No	2 Years	75
Merrell Internal Report 37	F	34	Amphetamine	Hysterical inadequate personality	No	4 Years	375

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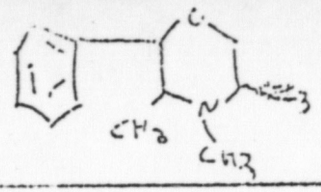
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PHENDIMETRAZINE - PLEGINE - 3,4-dimethyl-2-phenylmorpholine



15 years - 6 references

LD_{50} mg/kg [1]	CNS Stimulant Activity [3]	Cardiovascular Effects [3]	Tachyphylaxis [2]	Toxicology [13]
Mice - IP - 195 Oral - 340 IV - 150 Rats - IP - 245 Oral- 175 SC - 455	Rats ED_{50} oral - 21 mg/kg Similar to phenmetrazine (26 mg/kg - Confirmed in rat actophotometry experiments- Less potent than diethylpropion. Anorexigenic activity in dogs. Slight potency in voluntary both consumption test in rats.	Anesthetized dog - no pressor effects at 1 [illegible] 4 mg/kg. Hypotension at 8 and 16 mg/kg. No EKG changes.	Present in rat blood pressure assay.	No tissue toxicity in rats given 10-90 mg/kg/day for 6.5 months. Dose related CNS stimulation. No tissue toxicity in dogs given 10-25 mg/kg/day for 6.5 months. Maximum tolerated dose est. 15 mg/kg. 20 mg/kg and up lethal

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Biochemical Effects [4]	Euphoria [3]	Abuse Information	Monkey Self-Admin.	NDA Examined
Increased norepi levels in rat brain. Failed to alter dopamine levels	Observed in a few patients	None	Not done	yes

PLEGINE

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Chlorphentermine - Pre Sate - p-chloro, alpha, alpha dimethyl phenethylamine

LD_{50} (limits) mg/kg	Toxicology
Mouse Oral 255(223-288)	Rats 0, 10, 30, 60, 90 mg/kg/day via diet for 18 months.
IV 55(51-58)	Decreased weight gain and food consumption at 30 mg/kg and up. No tissue toxicity.
IP 112	
SC 150	Dogs - 0, 5, 10, 20 mg/kg/day by capsule for 18 months. No effect on behavior, growth rate, food consumption or weight gain.
Rat Oral 230(177-299)	
Hamster Oral 135	No tissue toxicity.
Rats & Mice LD_{50} - 1/8 that of d-amphetamine	

CNS Pharmacology

CNS stimulation in rats and mice - d-amphetamine most potent; chlorphentermine least potent. [1]

CNS stimulation & toxicity in rats - 12 compounds compared - Doxedrine ranked first in potency & toxicity; chlorphentermine 9th, fenfluramine 12th. [2]

Rats - Acute administration produced weight loss in rats but no increase in motor activity (50 mg/kg). Failed to alter hexobarb. sleep time. [3]

Rats, dogs, mice - Reduced food intake in rats, dogs, mice and aurothioglucose obese mice. Anorectic potencies - 0.2 in rats compared to d-amphetamine. 0.1 in dogs compared to d-amphetamine. chlorphentermine - depressed food intake in control and aurothioglucose-obese mice with a delayed onset and prolonged duration of action and without increase in locomotor activity. Tolerance to repeated injections.

In rats d-amphetamine 10 X as potent as chlorphentermine in food motivated operant behavioral tests. [5]

Chlorphentermine - 2.5 - 10 mg/kg IV produced EEG pattern in rabbits compatible to sedation. [8]

Reduced or stollshed arousal reaction produced by stimulation of the mesencephalic reticular activating system. [6]

Rats prepared with chronically implanted electrodes in lateral hypothalamus. Current necessary to elicit eating in these animals after they had been freely fed was measured. Chlorphentermine (also amph. metamph., diethylpropion, preludin) elevated current intensity necessary to elicit eating in dose related manner. [7]

Chlorphentermine given IP, IV or intracisternally to mice, rats or rabbits produced a catatonic response. [3]

Cardiovascular Studies

Chlorphentermine 26 mg/kg per day for 5 days produced a blood pressure rise on day 1 & 2 and a pronounced decrease from day 3 on. [9]

Cardiovascular profile in dogs similar to d-amphetamine and diethylpropion. Depressed vascular smooth muscle in vitro and in vivo. [10] Did not potentiate pressor responses to norepinephrine (amphetamine and diethylpropion did) [11]

10 anorexigenics tested in isolated guinea pig heart.

All these decreased coronary flow & produced negative inotropic effect. Fenfluramine most potent; chlorphentermine 2nd, amphetamine 10th in potency. [12]

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Biochemical Studies	Metabolism	Human Studies	Clinical Data Indicative of Euphoria	Narcotic Properties [12]
Chlorphentermine increased plasma free fatty acids in the rat. Could be blocked by reserpine in one expt and not in a second experiment. The effect could also be blocked by phenoxybenzamine. [14] In anesthetized or non anesthetized rats chlorphentermine increased O_2 consumption. [16] Chlorphentermine failed to mobilize lipids from fat adipose tissue. [15] Chlorphentermine injected into rats raised plasma free fatty acids. On an equimolar basis d-amphetamine was 10 times as potent. Orally in rats chlorphentermine IV raised free fatty acid levels but not glucose. [18] [17] Brain, heart, fat & spleen levels of norepinephrine were not altered by chlorphentermine. In several animal species chlorphentermine inhibited free fatty acid and glycerol release in rat and human adipose tissue. Phenmetrazine produced the opposite effect. [19]	Chlorphentermine given IVD rats; IM to rabbits and pigs. Highest levels in lung then spleen, adrenals, heart, kidneys & liver. Half life in rat = 231.5 minutes. [20] In man & dogs chlorphentermine excreted slowly in urine of 4-5 days (dogs) or 10 days (man). The drug was not metabolized. In rats chlorphentermine was found mainly in the adrenals, lung kidneys & spleen. [21] Rats - High levels of unchanged chlorphentermine in rats & prolonged retention time. No storage in adipose tissues. Rats excreted 70-90% of given dose via urine as unchanged drug. Female mice excreted 20% unchanged drug, 60% as an acidic conjugate and 15% as an unknown metabolite. Hydrolysis of the conjugate yielded chlorphentermine. [22]	In various psychological tests chlorphentermine & d-amphetamine showed similar effects. Chlorphentermine was longer lasting. Side effects of a mild degree included drowsiness, relaxation, dizziness, weakness of extremities, detached & unreal feelings and restless agitation. [23] In normal males the EEG alpha blocking response to photic stimulation was not blocked. [24] Chlorphentermine was about equivalent to d-amphetamine as an anorexigenic agent over 16 weeks in 29 obese patients. Side effects included nausea, vomiting, dizziness and drowsiness. [25]	No stimulation pattern and elevated mood states such as friendliness, self-assertiveness and involvement with surroundings and happenings. [12]	Chlorphentermine failed to substitute for morphine in morphine dependent monkeys.

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...nkey Self - Administration 13	Evidence of Abuse	DDA Looked at
...o reinforcement of self-administration ...havior.	1. An emotionally unstable and immature girl who had previously taken d-amphetamine and Preludin took up to 10 tablets day on and off for 9 months. She got a "lift" from it "though much less" than d-amphetamine and phenmetrazine. 12	No.
	2. Two cases from Denmark. No details.	
	3. One case where chlorphentermine was used as a narcotic. 12	
	4. One overweight psychiatric patient had to be readmitted to the hospital despite satisfactory weight loss (5 kg in 3 months) and treatment had to be discontinued by the nursing staff. 12	

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Form DJ-140
(Ed. 4-26-62)

UNITED STATES GOVERNMENT

DEPARTMENT OF JUSTICE

Memorandum

TO : John E. Ingersoll
Director

DATE: April 2, 1973

FROM : William W. Vodra
Assistant Chief Counsel

SUBJECT: Non-controlled anorectic drugs.

Attached is a copy of the memorandum prepared for the use of the Drug Control Committee in evaluating what the Bureau policy on anorectics should be. It contains all the alternatives we can determine and sketches the factors considered. The unanimous recommendation of the Drug Control Committee was to follow the FDA recommendation (Option 1) if we determine that FDA could substantiate claims of similarity among the drug. On Friday, March 30, Dr. Zendzian, Dr. Potrepka and I spent several hours at FDA covering these questions and were satisfied that the claims could be supported.

We will be able to go over these materials in detail at our meeting at 3 o'clock on Tuesday, April 3.

cc: Robert Rosthal

Mr. Vodra
Action per our meeting 4/3/73

6

April 2, 1973

John E. Ingersoll
Director

William W. Vodra
Assistant Chief Counsel

Non-controlled anorectic drugs.

Attached is a copy of the memorandum prepared for the use of the Drug Control Committee in evaluating what the Bureau policy on anorectics should be. It contains all the alternatives we can determine and sketches the factors considered. The unanimous recommendation of the Drug Control Committee was to follow the FDA recommendation (Option 1) if we determine that FDA could substantiate claims of similarity among the drug. On Friday, March 30, Dr. Zendzian, Dr. Potrepka and I spent several hours at FDA covering these questions and were satisfied that the claims could be supported.

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cc: Robert Rosthal

MEMORANDUM of MEETING

SUBJECT: Control of Anorectic Drugs March 13, 1973

Attending:

Mr. Kerness	ENAE
Mr. Persinger	ENAE
Mr. Vodra	CC
Dr. Smith	DMD
Mr. Carabillo	SCID
Dr. Lawrence	SCID
Dr. Potrepka	SCID
Dr. Zendzian	SCID

This meeting was held to coordinate BNDD's response to the HEW recommendation for control of the anorectic drugs, diethylpropion, benzphetamine, phendimetrazine, phentermine, chlorphentermine, clortermine, fenfluramine and mazindole. The latter three drugs are not yet marketed in the USA. HEW has recommended that all of these drugs be placed in Schedule III except fenfluramine which is recommended for Schedule IV.

The attendees reviewed the information presented by HEW and information presented by SCID, CC and ENA representatives.

SCID in October 1972 completed a preliminary study of the five (5) marketed drugs. The information collected at that time was not considered sufficient to justify a control recommendation but none of the information could support a case against control. Where information was available it showed that these drugs possessed qualities similar to amphetamine with possible quantitative differences.

CC and ENA have obtained preliminary information that indicates recent diversion of diethylpropion, benzphetamine, phendimetrazine and phentermine. CC presented information that some physicians were prescribing these anorectics with the express purpose of supplying stimulants, since amphetamines are not easily available. SCIL has recently received several letters from state laboratories that have identified phendimetrazine in street samples.

The information presented by HEW consisted of a summary of the information which they used to make their recommendation. While the summary information was considered insufficient by SCID it was considered to indicate that HEW (i.e., FDA) has sufficient information to justify their recommendation. Since the individuals at FDA, who contributed to the HEW recommendation,

will be utilized as expert witnesses at any required hearings, representatives of CC and SCID will interview the individuals concerned and access the quality and magnitude of the information which they have.

On the basis of the information available the attendees formulated seven options for consideration by BNDD. These options are:

1. Accept the HEW recommendations, placing all the drugs in Schedule III except fenfluramine in Schedule IV.
2. Place all the drugs in Schedule IV.
3. Place all the drugs in Schedule III.
4. Place all the drugs in Schedule II.
5. Place 4 of the drugs in Schedule III and 4 in Schedule IV.
6. Do not control the drugs.
7. No recommendation at this date, but rather dig in for more data.

Detailed outlines of the considerations for and against each option are attached. The attendees considered options #4 and #6 as unrealistic, and further that they could not justify placing fenfluramine in Schedule III and, therefore, option 3 was unrealistic. Option 7 was considered undesirable since it would require an excessive use of BNDD manpower.

As for recommending a particular choice among options 1,2 and 5, the ENA, DMD and SCID representatives considered option one as their first choice and were split in recommending between options 2 and 5. CC expressed its opinion on selecting options as follows:

> "Regarding selection of the options, Chief Counsel's office is of the opinion that action now is important for a variety of reasons. It is not crucial at this time to select between options 1, 2 and 5 (which are the most realistic alternatives) until we have commenced discussions with the drug companies and get a better feeling for the possibilities of having and winning hearings. We should enter discussions from the standpoint of the FDA recommendation in indicating a general Bureau philosophy that these drugs should be controlled "in line with FDA's recommendation." If the discussions indicate a high probability of hearings and therefore will require an extensive work-up by SCI and ENA of data now in the hands of FDA and federal, state and local agencies in the field, then we can consider other alternatives."

The Drug Control Committee's attention is directed to the need for expeditious handling of this matter. FDA is voluntarily withholding the New Drug Applications on the three new products to support our drug control efforts. The only grounds on which they can do this for any length of time is that we have commenced action to control and until that action is completed these drugs should not be made available to the American people. If BNDD delays commencing control

proceedings, the FDA position becomes untenable and they will have to permit the marketing of these three drugs. In addition the manufacturers of the five (5) presently marketed drugs are aware that BNDD has received HEW's recommendation to control their drugs and any excessive delay on our part will only serve to convince them that BNDD lacks substantial evidence for their control.

Option 1 Accept HEW recommendations
(All in Schedule III except fenfluramine in IV)

Hearing Possibilities	Manf. Request	BNDD Winning
Diethylpropion Tenuate	moderate	high
Benzphetamine Didrex	low	high
Phendimetrazine (withdrawn from market)	low	high
Phentermine Streptomycin (Lonamin)	low/moderate	high
Chlorphentermine	moderate	moderate
Clortermine	low	moderate
Mazindole Sandoz (Sandoz)	low	low/moderate
Fenfluramine A.H. Robbins	none	moderate/high

Cost of Control by BNDD

Regulatory, minimal
Criminal, low in present BNDD priorities
can be extensive if priorities change
Minimal Headquarters work-up (CC, SCID, ENA)

Pros and Cons of Option 1

Pros

rapid response
use HEW witnesses
minimize BNDD costs in scheduling
scheduling based on potential for abuse
conservative action
protect public
concur with FDA

Cons

not a serious problem now
follows FDA philosophy
uncertainty of success on 4 of 8 drugs
AMA will probably object

Option 2 Place all in Schedule IV

Hearing Possibilities	Manf. Request	BNDD Winning
Diethylpropion	none/low	high
Benzphetamine	none/low	high
Phendimetrazine	none/low	high
Phentermine	none/low	high
Chlorphentermine	low	high
Clortermine	low	high
Mazindole	low	moderate/high
Fenfluramine	moderate	moderate/high

Cost of Control by BNDD

Regulatory, minimal
Criminal, low in present BNDD priorities
can increase if priorities change
Minimal Headquarters work-up (CC, SCID, ENA)

Pros and Cons of Option 2

Pros

IV is holding schedule (compatible with unwritten BNDD philosophy)
rapid control - no hearings
sufficient evidence for IV
will be reviewed for increased control
defensible in law and fact

Cons

back to HEW
take more time
actual diversion of at least 4 drugs
weakness in future negotiations
public disagreement with FDA
appear soft on these drugs
may require greater BNDD effort to move to II if regulatory controls were insufficient

important / exp. of FDA / Federal Register

Option 3 Place all in Schedule III

Hearing Possibilities

	Manf. Request	BNDD Winning
Diethylpropion	low	high
Benzphetamine	low	high
Phendimetrazine	low	high
Phentermine	low	high
Chlorphentermine	low	high
Clortermine	low	high
Mazindole	low	low/moderate
Fenfluramine	high	low

Cost of Control by BNDD

Regulatory, minimal
Criminal, low in present BNDD priorities
can be extensive if priorities change
Extensive Headquarters work-up (SCID & CC)

Pros and Cons of Option 3

Pros

fenfluramine has possible stimulating effects and could be unique new drug experience
scheduling based on potential for abuse
protect public (conservative approach)

Cons

back to HEW
doubtful win for fenfluramine without extensive work-up
not a serious problem now

Option 4 Place all in Schedule II
(Attendants did not consider this option realistic)

Hearing Possibilities

	Manf. Request	BNDD Winning
Diethylpropion	high	low
Benzphetamine	high	low
Phendimetrazine	moderate	moderate
Phentermine	high	low
Chlorphentermine	high	low
Clortermine	high	low
Mazindole	high	low
Fenfluramine	high	low

Cost of Control by BNDD

Regulatory, quotas, ARCOS, order forms, registration
Criminal, lower than placing these drugs in Schedule III within present priorities
Extensive Headquarters work-up (ENA, CC, SCID)

Pros and Cons of Option 4

Pros

eliminate diversion
most effective controls

Cons

back to HEW
time consuming
excessive manpower requirements
must fight in hearings
extensive BNDD work-up required
cannot justify
AMA will object

Option 5 — Place 4 drugs in III and 4 in IV (See below)

Hearing Possibilities

Schedule		Manf. Request	BNDD Winning
III	Diethylpropion	moderate/high	high
III	Benzphetamine	low/moderate	high
III	Phenmetrazine	low/moderate	high
III	Phentermine	moderate	high
IV	Chlorphentermine	low	high
IV	Clortermine	low	high
IV	Mazindole	low	low/moderate
IV	Fenfluramine	low/moderate	low/moderate

Cost of Control by BNDD

Regulatory, minimal
Criminal, low in present BNDD priorities
can be extensive if priorities change
Minimal Headquarters work-up (CC, SCID, LEA)

Pros and Cons of Option 5

Pros

relates to actual diversion in Schedule III
holding in Schedule IV
scheduling based on potential for abuse
protect public (conservative approach)
easy to move III to II if diversion increases
easy to move IV to III if some diversion appears

Cons

back to HEW
moving from IV to II may be difficult

Option 6 — No Control
(Attendants consider this option unrealistic)

Hearing Possibilities

None

Cost of Control by BNDD

None

Pros and Cons of Option 6

Pros

None

Cons

indefensible for diethylpropion, benzphetamine, phendimetrazine and phentermine due to known diversion
public reaction
petitions to control may be expected from the public

Option 7 No recommendation at this date

1. request further material from HEW
2. develop more information in-house
3. develop philosophy of control first

Pros and Cons of Option 7

Pros

Compels development of a philosophy

More data will be available for decision

Cons

Lose HEW assistance

Delay in control

Large BNDD work-up for small problem

[21 CFR Part 308]

SCHEDULES OF CONTROLLED SUBSTANCES

Proposed Placement of Phentermine in Schedule III

On February 15, 1973, the Acting Assistant Secretary for Health, on behalf of the Secretary of Health, Education, and Welfare, sent the following letter to the Director of the Bureau of Narcotics and Dangerous Drugs:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

OFFICE OF THE SECRETARY

Washington, D.C. 20201

FEBRUARY 15, 1973.

JOHN E. INGERSOLL,
Director, Bureau of Narcotics and Dangerous Drugs, Department of Justice, 1405 I Street NW., Washington, D.C. 20537

DEAR MR. INGERSOLL: The Food and Drug Administration has recently completed a review of all drugs currently marketed or proposed for marketing in the United States for the treatment of obesity. The marketed drugs include three substances already controlled under schedule II of the Controlled Substances Act, amphetamine, methamphetamine, and phenmetrazine. The review also included drugs currently not controlled under any schedule, the marketed drugs, diethylpropion, benzphetamine, phendimetrazine, phentermine, and chlorphentermine, and the investigational substances, clortermine, mazindol, and fenfluramine. New drug applications have been submitted to the Food and Drug Administration for the latter three drugs, and approval is pending.

Review of data reveals that these drugs produce approximately the same degree of therapeutic effects in man as currently scheduled anorectics, as adjuncts in weight reduction in the obese. The review indicated that the drugs are also comparable in other ways to scheduled anorectics:

a. They are all closely related chemically, with the exception of mazindol.

b. Their pharmacological profiles are closely similar, except for certain aspects of the profile of fenfluramine.

c. Documentation of actual abuse or production of dependence in humans is irregular, but does exist for certain of the unscheduled anorectics. The skimpy documentation of abuse of these drugs appears due to the fortuitous nature of reports as currently obtained and to the past easy availability of cheaper and more potent stimulants, rather than to intrinsic lack of abuse potential.

d. We note the conclusions and recommendations of the WHO Expert Committee on Drug Dependence that these drugs either be subject to control or by analogy are similar to drugs recommended for control.

e. Certain specialized testing of fenfluramine suggests that the abuse potential of fenfluramine is of a lower order of magnitude than that of the other drugs under consideration.

We, therefore, conclude that all the above named drugs possess abuse potential and potential for producing drug dependence, and are so informing you as required under the provisions of section 201(f) of the Controlled Substances Act. As provided for by section 201(a), we further request that the Attorney General initiate rules adding the above drugs to the schedules of the Controlled Substances Act, and recommend that the schedule for all drugs but fenfluramine be schedule III, fenfluramine appearing more appropriately controlled under the provisions of schedule IV.

We attach review material assembled by reviewing pharmacologists within the Food and Drug Administration for its possible utility to you, and as a basis for further discussion after your scientists have reviewed our recommendations and request.

Sincerely,

RICHARD L. SEGGEL,
Acting Assistant Secretary for Health.

Upon receipt of this letter, the Bureau undertook a review of the following: (1) Materials submitted to BNDD by the Department of Health, Education, and Welfare with the letter of February 15, 1973; (2) materials submitted to the Food and Drug Administration in connection with new drug applications on these drugs; (3) published scientific and medical literature from the United States and other nations regarding these drugs; (4) selected investigatory files compiled for law enforcement purposes by the Bureau and another law enforcement agency; and (5) the legislative history of the Controlled Substances Act.

The results of this review can be summarized as follows:

(1) Phentermine is chemically similar to and related to the other anorectic drugs being proposed for control, and to amphetamine, methamphetamine, and phenmetrazine, substances currently listed in schedule II.

(2) Phentermine has a pharmacological profile which is similar to the other anorectic drugs being proposed for control and to amphetamine, methamphetamine, and phenmetrazine. This general similarity suggests that all of these drugs may be reasonably substituted for each other for therapeutic or abuse purposes.

(3) Phentermine is covered by a new drug application approved by the Food and Drug Administration for use in treatment of obesity.

(4) Products containing benzphetamine, chlorphentermine, diethylpropion, phendimetrazine, or phentermine have been marketed in the United States for several years. In the last 6 months, certain of these products have been reported as the subject of thefts, diversion, illicit sales, and abuse. Quantitatively, this data does not suggest a widespread problem at the present time; qualitatively, the data indicates a trend to substitute these products for amphetamine and methamphetamine preparations in abuse circles. This reinforces the belief that abuse of the pharmacologically similar drugs will increase as the amphetamines and methamphetamine become less and less available.

(5) The legislative history of the Controlled Substances Act makes clear that the Bureau is to schedule drugs based upon their potential for abuse, and "should not be required to wait until a number of lives have been destroyed or substantial problems have arisen before designating a drug as subject to controls." (Comprehensive Drug Abuse Prevention and Control Act of 1970, House Report 91-1444 (part 1), p. 35, Sept. 10,

1970.) Discussing factors used to measure potential for abuse, the report quotes from the regulations issued under the Drug Abuse Control Amendments of 1965 (id. at p. 34):

The Director may determine that a substance has a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect if:

(1) There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community; or

(2) There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or

(3) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice.

The House report goes on to say (id. at p. 35):

In speaking of "substantial" potential [for abuse] the term "substantial" means more than a mere scintilla of isolated abuse, but less than a preponderance. Therefore, documentation that, say, several hundred thousand dosage units of a drug have been diverted would be "substantial" evidence of abuse despite the fact that tens of millions of dosage units of that drug are legitimately used in the same time period.

The Director has concluded from this review of the current situation that control of all anorectic drugs is desirable at this time to insure that they will not become widely abused. This scheduling will fulfill the congressional mandate to act before substantial problems have arisen.

Based upon the investigations and review of the Bureau of Narcotics and Dangerous Drugs and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to sections 201 (a) and (b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811 (a), (b)), the Director of the Bureau of Narcotics and Dangerous Drugs finds that:

1. Based on information now available, phentermine has a potential for abuse less than the drugs or other substances currently listed in schedule II. Although chemically and pharmacologically this drug is closely related to the other anorectic drugs being proposed for control and to the stimulants now listed in schedule II, present data regarding excessive usage, diversion, illicit sales, and abuse of phentermine is not substantial enough to warrant a finding that it has potential for abuse equal to the stimulants in schedule II.

2. Phentermine has a currently accepted medical use in treatment in the United States.

3. Abuse of phentermine may lead to high psychological dependence.

Therefore, under the authority vested in the Attorney General by section 201 (a) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a), and delegated to the Director of the Bureau of Narcotics and Dangerous Drugs by § 0.100 of title 28 of the Code of Federal Regulations, the Director proposes that § 308.13 of title 21 of the Code of Federal Regulations be amended to read:

§ 308.13 Schedule III.

• • • • •

(b) *Stimulants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in schedule II which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under § 308.32, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances	1405
(2) Phentermine	1640

• • • • •

Conferences have been held between the Bureau and the Dorsey Laboratories, Division of Sandoz-Warner, Inc., one of the two manufacturers of phentermine in the United States. Dorsey has fully cooperated with the Bureau and has consented to the placement of phentermine in schedule III to insure that it does not become subject to abuse in the future.

All other interested persons are invited to submit their comments or objections in writing regarding this proposal. These comments or objections should state with particularity the issues concerning which the person desires to be heard. Comments and objections should be submitted in quintuplicate to the Hearing Clerk, Office of Chief Counsel, Bureau of Narcotics and Dangerous Drugs, Department of Justice, room 611, 1405 Eye Street NW., Washington, D.C. 20537, and must be received no later than June 7, 1973.

In the event that an interested party submits objections to this proposal which present reasonable grounds for this rule not to be finalized and requests a hearing in accordance with 21 CFR 308.45, the party will be notified by registered mail that a hearing on these objections will be held at 10 a.m. on June 11, 1973, in room [illegible], 1405 Eye Street, NW., Washington, D.C. 20537. If objections submitted do not present such reasonable grounds the party will be so advised by registered mail.

If no objections presenting reasonable grounds for a hearing on the proposal are received within the time limitations, and all interested parties waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the

Director may cancel the hearing and, giving consideration to written comments, issue his final order pursuant to 21 CFR § 308.48 without a hearing.

Dated May 1, 1973.

JOHN E. INGERSOLL,
Director, Bureau of Narcotics and Dangerous Drugs.

[FR Doc.73-9070 Filed 5-8-73;8:45 am]

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...such food transportation is not used the ... evidence of Part 903 will ... more than harmless ...

...does not impose any burden upon ... but merely constitutes an ... to the Board's regulations of ... interpretative and technical nature, ... so as to render them consistent with ... Postal Reorganization Act. The Board ... that notice and public procedure ... thereon are unnecessary, and the amendment may become effective forthwith.

In consideration of the foregoing, the Civil Aeronautics Board hereby amends and reissues Part 223 of its Economic Regulations (14 CFR Part 223), effective June 12, 1973, as follows:

Sec.
223.1 Postal employees to be carried free.
223.2 Issuance of credentials and authorization of travel by Postal Service.

AUTHORITY.—Secs. 204(a) and 405(f) of the Federal Aviation Act of 1958, as amended, 72 Stat. 743, 760; 49 U.S.C. 1324, 1375; sec. 2 of the Postal Reorganization Act, 84 Stat. 767; 39 U.S.C. 5007.

§ 223.1 Postal employees to be carried free.

Every air carrier transporting the mails shall carry, on any flight that it operates and without charge therefor, persons on duty in charge of the mails or traveling to or from such duty, upon the exhibition of their credentials.

§ 223.2 Issuance of credentials and authorization of travel by Postal Service.

With regard to free air travel by the persons described in § 223.1, the Postmaster General shall be responsible for: (a) The issuance of proper credentials for such persons and (b) the authorization of travel by such persons, subject to such rules and regulations as he may prescribe.

By the Civil Aeronautics Board.

[SEAL] EDWIN Z. HOLLAND,
Secretary.

[FR Doc.73-11978 Filed 6-14-73;8:45 am]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER C—DRUGS

PART 135c—NEW ANIMAL DRUGS FOR OPHTHALMIC AND TOPICAL USE

Chloramphenicol Ophthalmic Ointment, Veterinary

The Commissioner of Food and Drugs has evaluated a new animal drug application (65-173V) filed by Vet-A-Mix Pharmaceutical Corp., 3315 Royal Avenue, Oceanside, N.Y. 11572, proposing the safe and effective use of chloramphenicol ophthalmic ointment veterinary, for the treatment of cats and dogs. The application is approved.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347; 21 U.S.C. 360b(i)) and under authority delegated to the Commissioner (21 CFR 2.120), part 135c is amended in § 135c.29 by revising paragraphs (b) and (c) as follows:

§ 135c.29 Chloramphenicol ophthalmic ointment, veterinary.

* * * * *

(b) *Sponsor.*—See code No. 049 for use in accordance with paragraph (c) (1) (i) and code No. 050 for use in accordance with paragraph (c) (1) (ii) in 510.600(c).

(c) *Conditions of use.*—(1) It is used in dogs and cats for treatment of bacterial ophthalmic infections caused by bacteria susceptible to chloramphenicol as follows:

(i) It is applied every 3 hours around the clock for 48 hours after which medication may be omitted. Treatment should be continued for 2 days after the eye appears normal.

(ii) It is applied to affected eye four to six times daily for the first 72 hours depending upon the severity of the condition. A small amount of ointment should be placed in the lower conjunctival sac. Continue treatment for 48 hours after eye appears normal.

(2) Therapy for cats should not exceed 7 days. Prolonged use in cats may produce blood dyscrasias. If improvement is not noted in a few days a change of therapy should be considered. When infection is suspected as the cause of a disease process especially in purulent or catarrhal conjunctivitis, attempts should be made to determine through susceptibility testing, which antibiotic will be effective prior to applying ophthalmic preparations. This antibacterial product must not be used in animals producing meat, eggs, or milk for the length of time that residues persist in milk or tissues has not been determined.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date.—This order shall be effective on June 15, 1973.

(Sec. 512(i), 82 Stat. 347; 21 U.S.C. 360b(i).)

Dated June 8, 1973.

C. D. VAN HOUWELING,
Director,
Bureau of Veterinary Medicine.

[FR Doc.73-11927 Filed 6-14-73;8:45 am]

CHAPTER II—BUREAU OF NARCOTICS AND DANGEROUS DRUGS, DEPARTMENT OF JUSTICE

PART 308—SCHEDULES OF CONTROLLED SUBSTANCES

Placement of Benzphetamine, Chlorphentermine, Clortermine, Diethylpropion, Mazindol, Phendimetrazine, and Phentermine in Schedule III, and Placement of Fenfluramine in Schedule IV

Notices were published in the FEDERAL REGISTER on May 9 and 16, 1973, proposing placement of benzphetamine (38 FR 12119), chlorphentermine (38 FR 12120), clortermine (38 FR 12121), diethylpropion (38 FR 12230), mazindol (38 FR 12121), phendimetrazine (38 FR 12120), and phentermine (38 FR 12121) in Schedule III of the Controlled Substances Act, and fenfluramine (38 FR 12123) in Schedule IV of the Controlled Substances Act. All interested persons were given until June 7, 1973, to file objections, comments, or requests for a hearing. A notice was published in the FEDERAL REGISTER on May 31, 1973, extending the time for filing to June 11, 1973 (38 FR 14238).

No objections nor requests presenting reasonable grounds for a hearing regarding the proposed orders on benzphetamine, chlorphentermine, clortermine, mazindol, and phendimetrazine were received. An objection and request for a hearing regarding the proposed orders on phentermine and fenfluramine was filed on May 21, 1973, and supplemented on June 11, 1973, by Pennwalt Corp. Details of these filings are discussed under the headings "Fenfluramine" and "Phentermine" below. An objection and request for a hearing regarding the proposed order on diethylpropion was filed on June 11, 1973, by Merrell National Laboratories, a division of Richardson Merrell, Inc. Details on this filing are discussed under the heading "Diethylpropion" below.

A comment was filed on May 23, 1973, by Lexington Chemical Co., Inc., Waltham, Mass., requesting that adequate time be provided between the publication of a final order and the effective date of such an order to provide industry sufficient opportunity to adjust to the new controls. The Bureau has considered this suggestion and believes that the effective dates set in this order comply with the spirit of the comment.

Benzphetamine

Based upon the investigations and review of the Bureau of Narcotics and Dangerous Drugs and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to section 201 (a) and (b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811 (a), (b)), the Director of the Bureau of Narcotics and Dangerous Drugs finds that:

1. Based on information now available, benzphetamine has a potential for abuse less than the drugs or other substances currently listed in schedule II. Although chemically and pharmacologically this drug is closely related to the other anorectic drugs now being controlled and to the stimulants now listed in schedule II, present data regarding excessive usage, diversion, illicit sales, and abuse of benzphetamine is not substantial enough to warrant a finding that it has a potential for abuse equal to the stimulants presently in schedule II.

2. Benzphetamine has a currently accepted medical use in treatment in the United States.

3. Abuse of benzphetamine may lead to moderate psychological dependence.

The Director has concluded from his review of the current situation that control of all anorectic drugs, including benzphetamine, is desirable at this time to insure that they will not become widely abused. This scheduling will fulfill the

gressional mandate to act before substantial problems have arisen. The Upjohn Co., the only manufacturer of benzphetamine in bulk or dosage form in the United States, has fully cooperated with the Bureau and has consented to the placement of benzphetamine in schedule III to insure that it does not become subject to abuse in the future.

CHLORPHENTERMINE

Based upon the investigations and review of the Bureau of Narcotics and Dangerous Drugs and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to sections 201 (a) and (b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811 (a), (b)), the Director of the Bureau of Narcotics and Dangerous Drugs finds that:

1. Based on information now available, chlorphentermine has a potential for abuse less than the drugs or other substances currently listed in schedule II. Although chemically and pharmacologically this drug is closely related to the other anorectic drugs now being controlled and to the stimulants now listed in schedule II, present data regarding excessive usage, diversion, illicit sales, and abuse of chlorphentermine is not substantial enough to warrant a finding that it has a potential for abuse equal to the stimulants in schedule II.

2. Chlorphentermine has a currently accepted medical use in treatment in the United States.

3. Abuse of chlorphentermine may lead to high psychological dependence.

The Director has concluded from his review of the current situation that control of all anorectic drugs, including chlorphentermine, is desirable at this time to insure that they will not become widely abused. This scheduling will fulfill the congressional mandate to act before substantial problems have arisen.

CLORTERMINE

Based upon the investigations and review of the Bureau of Narcotics and Dangerous Drugs and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to sections 201(a) and (b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a), (b)), the Director of the Bureau of Narcotics and Dangerous Drugs finds that:

1. Based on information now available, clortermine has a potential for abuse less than the drugs or other substances currently listed in schedule II. Although chemically and pharmacologically this drug is closely related to the other anorectic drugs now being controlled and to the stimulants now listed in schedule II, present data regarding these properties is not substantial enough to warrant a finding that it has a potential for abuse equal to the stimulants in schedule II.

2. Clortermine will, upon the approval of new drug application by the FDA, have a currently accepted medical use in treatment in the United States.

3. Abuse of clortermine may lead to high psychological dependence.

The Director has concluded from his review of the current situation that control of all anorectic drugs, including clortermine, is desirable at this time to insure that they will not become widely abused. This scheduling will fulfill the congressional mandate to act before substantial problems have arisen. The USV Pharmaceutical Corp., the only firm intending to market clortermine in the United States, has fully cooperated with the Bureau. Upon the conditions set forth in a letter to the Bureau from counsel for USV Pharmaceutical Corp. dated April 29, 1973, the manufacturer has consented to the placement of clortermine in schedule III to insure that it does not become subject to abuse in the future.

DIETHYLPROPION

The Bureau proposed placement of diethylpropion in schedule III, because it is one of the anorectics, control of which is desirable at this time (38 FR 12127).

Merrell National Laboratories, a division of Richardson-Merrell, Inc., the only manufacturer of diethylpropion in the United States, filed comments, objections, and a request for a hearing regarding diethylpropion on June 11, 1973. In light of these objections and request for a hearing, the Director will not issue a final order controlling diethylpropion at this time.

FENFLURAMINE

The Pennwalt Corp., a manufacturer of a phentermine product called "Ionamin", filed comments, objections, and a request for a hearing regarding phentermine and fenfluramine on May 21, 1973. The comments of Pennwalt Corp. include the following paragraphs:

Pennwalt Corp. has no objection to the scheduling of "Ionamin" in schedule III, provided that the same scientific and legal principles which would lead to this scheduling of "Ionamin" are also applied to any other relevant product. Our objection, specifically, is that on the basis of information available to Pennwalt Corp. and to the field generally, there would appear to be more than, or at least an equal basis for placing fenfluramine in an equal or more restrictive schedule than "Ionamin".

It is Pennwalt's position that the Department of Health, Education, and Welfare erred in recommending to the DSCD that the products listed above, except for fenfluramine, be placed in schedule III, and that fenfluramine be placed in schedule IV. The basis for Pennwalt's position is twofold:

1. To the best of Pennwalt's knowledge, information and belief, the record of "Ionamin" with respect to abuse of any adverse consequences known to us do not warrant [illegible] any requirement [illegible] schedule [illegible] "Ionamin" [illegible] the level of [illegible] currently [illegible] for the [illegible] fenfluramine.

2. The evidence with respect to the use of fenfluramine in Holland, South Africa, and [illegible] the policy [illegible] and the actions which [illegible] symptoms [illegible] the use of fenfluramine in controlled studies.

[The exhibits submitted by Pennwalt omitted.]

Pennwalt is aware that the Bureau of Narcotics and Dangerous Drugs, and presumably the Department of Health, Education, and Welfare, were aware of possible abuse in South Africa, as stated at page 12123 of the Federal Register, volume 38, No. 89, but Pennwalt believes that the material transmitted herewith demonstrates the basis upon which evaluation of fenfluramine should be made, when compared to the other products noted above.

In summary, fenfluramine appears to be the only product as to which there is serious adverse medical literature of record, and Pennwalt therefore believes that, as noted above, the scheduling of fenfluramine should be at no more permissive schedule than provided for the other relevant products.

On June 1, 1973, the Bureau notified Pennwalt Corp. that no objection had been raised regarding the control of fenfluramine, but only to the propriety of its placement in schedule IV. The Bureau interpreted this objection as a proposal to control fenfluramine in schedule III or, if fenfluramine is controlled in schedule IV as proposed, a petition to transfer fenfluramine from schedule IV to schedule III. Pennwalt Corp. was informed that, unless the company requested otherwise, the Bureau would consider the comments as a petition to place fenfluramine in schedule III and not as an objection to the current proposal to place fenfluramine in schedule IV. (A hearing on the proper schedule for fenfluramine would therefore be held only after receipt of the report of the Secretary of Health, Education, and Welfare, which has been [illegible] Pennwalt Corp. has not [illegible] tions have been received regarding the fenfluramine proposal.

Based upon the investigations and review of the Bureau of Narcotics and Dangerous Drugs and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to sections 201 (a) and (b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811 (a), (b)), the Director of the Bureau of Narcotics and Dangerous Drugs finds that:

1. Based on information evaluated up to this time, fenfluramine has a low potential for abuse relative to the drugs or other substances currently listed in schedule III. Although chemically and/or pharmacologically this drug is related to the other anorectic drugs now being controlled and to the stimulants now listed in schedule II, present data regarding excessive usage, diversion, illicit sales, and abuse in other countries is not substantial enough to warrant a finding that fenfluramine has a potential for abuse equal to the stimulants in schedule II or to the other anorectic drugs now being controlled in schedule II. In addition, certain information cited in the letter from the Department of Health, Education, and Welfare appears to have a low abuse potential for fenfluramine.

2. Fenfluramine will, upon the approval of a new drug application by the FDA, have a currently accepted medical use in treatment in the United States.

3. Abuse of fenfluramine may lead to limited physical dependence relative to the drugs or other substances in schedule III.

In making these findings, the Director is aware that material filed by the Pennwalt Corp., material previously referred to the Department of Health, Education, and Welfare for evaluation concerning possible abuse of fenfluramine in South Africa (see 38 FR 12173, May 9, 1973), and other evidence which may become available might necessitate findings regarding the abuse potential and dependence liability of fenfluramine justifying placement of the substance in schedule III. Therefore, the findings made in this order should not be construed as precluding new findings regarding fenfluramine in the near future in light of such evidence.

The Director has concluded from his review of the current situation that control of all anorectic drugs, including fenfluramine, is at this time to prevent their becoming widely abused. This scheduling will fulfill the congressional mandate to act before substantial problems have arisen. The A. H. Robins Co., the only firm intending to market fenfluramine in the United States, has fully cooperated with the Bureau and has consented to the placement of fenfluramine in schedule IV to insure that it does not become subject to abuse in the future.

MAZINDOL

Based upon the investigations and review of the Bureau of Narcotics and Dangerous Drugs and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to sections 201 (a) and (b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811 (a) and (b)), the Director of the Bureau of Narcotics and Dangerous Drugs finds that:

1. Based on information now available, mazindol has a potential for abuse less than the drugs or other substances currently listed in schedule II. Although pharmacologically this drug is closely related to the other anorectic drugs now being controlled and to the stimulants now listed in schedule II, present data regarding these properties is not substantial enough to warrant a finding that it has a potential for abuse equal to the stimulants in schedule II.

2. Mazindol will, upon the approval of a new drug application by the Food and Drug Administration, have a currently accepted medical use in treatment in the United States.

3. Abuse of mazindol may lead to high psychological dependence.

The Director has concluded from his review of the current situation that control of all anorectic drugs, including mazindol, is desirable at this time to insure that they will not become widely abused. This scheduling will fulfill the congressional mandate to act before substantial problems have arisen. Sandoz-Wander, Inc., the only firm intending to market mazindol in the United States, has fully cooperated with the Bureau and has consented to the placement of mazindol in schedule IV to insure that it does not become subject to abuse in the future.

PHENDIMETRAZINE

Based upon the investigations and review of the Bureau of Narcotics and Dangerous Drugs and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to sections 201(a) and (b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811 (a), (b)), the Director of the Bureau of Narcotics and Dangerous Drugs finds:

1. Based on information now available, phendimetrazine has a potential for abuse less than the drugs or other substances currently listed in schedule II. Although chemically and pharmacologically this drug is closely related to the other anorectic drugs now being controlled and to the stimulants now listed in schedule II, present data regarding excessive usage, diversion, illicit sales, and abuse of phendimetrazine is not substantial enough to warrant a finding that it has a potential for abuse equal to the stimulants in schedule II.

2. Phendimetrazine has a currently accepted medical use in treatment in the United States.

3. Abuse of phendimetrazine may lead to high psychological dependence.

The Director has concluded from his review of the current situation that control of all anorectic drugs, including phendimetrazine, is desirable at this time to insure that they will not become widely abused. This scheduling will fulfill the congressional mandate to act before substantial problems have arisen. The Ayerst Laboratories Division of the American Home Products Corp., the largest manufacturer of phendimetrazine in the United States and the only firm with a new drug application for phendimetrazine approved by the Food and Drug Administration, has fully cooperated with the Bureau and has consented to the placement of phendimetrazine in schedule III to insure that it does not become subject to abuse in the future.

PHENTERMINE

The Bureau proposed placement of phentermine in schedule III, because it is one of the anorectic control of which is desirable at this time. (38 FR 12167).

The Dorsey Laboratories, Division of Sandoz-Warner, Inc., one of the two manufacturers of phentermine in the United States, has fully cooperated with the Bureau and has consented to the placement of phentermine in schedule III to insure that it does not become subject to abuse in the future.

Pennwalt Corp., the other manufacturer of phentermine in the United States, filed comments, objections, and a request for a hearing regarding phentermine and fenfluramine on May 21, 1973. The major portion of these comments were set forth above under the heading "Fenfluramine." On June 11, 1973, Pennwalt Corp. supplemented its above regarding its objections on phentermine. In light of these objections and request for a hearing, the Director will not issue a final order controlling phentermine at this time.

CONCLUSION

Therefore, under the authority vested in the Attorney General by section 201(a) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a)), and delegated to the Director of the Bureau of Narcotics and Dangerous Drugs by § 0.100 of title 28 of the Code of Federal Regulations, the Director orders that:

1. Paragraph (b) of § 308.13 of title 21 of the Code of Federal Regulations be amended to read:

§ 308.13 Schedule III.

* * * * *

(b) *Stimulants.*—Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in schedule II which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under § 308.32, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances	1405
(2) Benzphetamine	1228
(3) Chlorphentermine	1645
(4) Clortermine	1647
(5) Mazindol	1605
(6) Phendimetrazine	1615

* * * * *

2. Section 308.14 of title 21 of the Code of Federal Regulations be amended by the addition of a new paragraph to read:

§ 308.14 Schedule IV.

* * * * *

(c) *Fenfluramine.*—Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible:

(1) Fenfluramine	1670

FUTURE ACTION REGARDING ANORECTICS

Because of the similarities among the substances controlled by this order, and between these substances and the stimulants currently listed in schedule II, the Director is controlling these substances at this time in order to prevent their becoming the subject of abuse as amphetamines become less available in the illicit

market through the operation of the [illegible] regulatory controls and criminal enforcement actions. The Director believes that evidence exists that these anorectics may be future targets of stimulant abusers.

The Bureau will monitor the manufacture, distribution, and use of benzphetamine, chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine in the United States, paying special attention to indicators of diversion (such as shortages in accountability audits of distributors and dispensers, thefts from handlers, and availability on the illicit market) and to other indicators which indicate that any of these substances are actually being abused (such as excessive prescribing and dispensing, reports of adverse reactions and overdoses, and other medical experiences).

The Bureau will also consider, if available, clinical and other research in abuse-ability, dependence-creating, and tolerance-sustaining characteristics of any of these substances. If, after 18 months during which these drugs are marketed, experience suggests that any of them have not been subject to significant diversion or abuse, the Director will review the necessity and desirability of maintaining it in schedule III (or, in case of fenfluramine, schedule IV) and will request from the Secretary of Health, Education, and Welfare a new scientific and medical evaluation, and his recommendation, as to whether that substance should be so controlled or removed as a controlled substance.

Any interested person may petition the Bureau to decontrol any of these substances at any time. If any petition is received to decontrol any one of these substances, or if the Director, based upon the review mentioned above, requests the evaluation and recommendation of the Secretary of Health, Education, and Welfare on any of these substances, all of the remaining substances will also be reviewed and, where appropriate, evaluations and recommendations regarding them will also be requested of the Secretary.

EFFECTIVE DATES

The requirements imposed upon the anorectic substances controlled by this order shall become effective as follows:

1. *Registration.*—Unless currently registered to conduct such activity with schedule III (or, in the case of fenfluramine, schedule IV) nonnarcotic substances, or unless exempted from registration by law, or pursuant to §§ 301.21-301.23 or 311.25-311.36 of title 21 of the Code of Federal Regulations, any person [illegible] imports, or exports benzphetamine, chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine, or who [illegible] on or before August 1, 1973.

2. *Security.* Benzphetamine, chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine must be manufactured, distributed, and stored in accordance with §§ 301.71, 301.72(a), 301.73, 301.74, 301.75(b), and 301.76 of title 21 of the Code of Federal Regulations on or before September 1, 1973. In the event that this poses special hardships, the Bureau will entertain any justified requests for extensions of time.

3. *Labeling and packaging.*—All labels on commercial containers of, and all labeling of, clortermine, fenfluramine, and mazindol which are packaged after June 13, 1973, shall comply with the requirements of §§ 302.03-302.05 and 302.06 of title 21 of the Code of Federal Regulations. In accordance with § 302.06 (c) of title 21 of the Code of Federal Regulations, the Director finds that early compliance with these requirements is necessitated by the fact that if these drugs, which have never before been marketed in the United States, fail to bear the appropriate symbol, physicians, pharmacists, distributors, and other handlers may not be aware that these drugs are now controlled under the Controlled Substances Act, thereby endangering the public health and safety. As noted above, early control of these substances has been undertaken to prevent abuse before it becomes widespread and adequate notice of control is essential to carry out this purpose.

All labels on commercial containers of, and all labeling of benzphetamine, chlorphentermine, and phendimetrazine which are packaged after September 1, 1973, shall comply with the requirements of §§ 302.03-302.05 and 302.06 of title 21 of the Code of Federal Regulations. In accordance with § 302.06(c) of title 21 of the Code of Federal Regulations, the Director finds that early compliance with these requirements is necessitated by the fact that early control of these substances has been undertaken to prevent abuse before it becomes widespread; prompt and adequate notice of control is essential to carry out this purpose and thereby protect the public health and safety. In addition, the Director believes it would be unfair and discriminatory to allow any greater period of time between the effective dates of labeling for the new anorectics and the effective dates for those anorectics already being marketed.

In the event these effective dates pose special hardships on any handler, the Bureau will entertain any justified requests for an extension of time.

4. *Inventory.*—Every registrant required to keep records who possesses any quantity of benzphetamine, chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine on the effective date of labeling for the new anorectics shall take an inventory of all stocks of these substances on hand.

5. *Records.*—All registrants required to keep records [illegible] which the inventory of these substances is taken.

6. *Prescriptions.*—All prescriptions for products containing benzphetamine, chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine shall comply with §§ 306.01-306.06 and 306.21-306.25 of title 21 of the Code of Federal Regulations no later than September 1, 1973. Any prescription for any of the foregoing products which was issued before March 1, 1973, or which has been refilled more than five times, may not be refilled after [illegible] 1, 1973.

7. *Importation and exportation.*—All importation and exportation of benzphetamine, chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine on and after September 1, 1973, shall be in compliance with part 312 of title 21 of the Code of Federal Regulations.

8. *Criminal liability.*—Any activity with benzphetamine, chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine, not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act, committed after June 15, 1973, shall be unlawful, except that any person who is not now registered to handle these substances but who is entitled to registration under these acts may continue to conduct such business or professional practice with these substances between the date on which this order is published and the date on which he obtains the proper registration.

9. *Other.*—In all other respects, this order is effective on June 15, 1973.

Dated June 12, 1973.

JOHN E. INGERSOLL,
Director, Bureau of Narcotics and Dangerous Drugs.

[FR Doc.73-11925 Filed 6-14-73;8:45 am]

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER C—AIR PROGRAMS

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Approval of Plan Revisions

On October 23, 1972 (37 FR 23085), pursuant to section 110(c) of the Clean Air Act, the Administrator promulgated regulations for several [illegible] revisions of plans submitted by the States. [illegible] new sources and modifications was promulgated for the State of New Jersey (37 [illegible] of the Clean Air Act and [illegible] plan.

[illegible] State of New Jersey on March 23, 1973, submitted amended chapters 9 (Permits) and 13 (Ambient quality standards) of the New Jersey Air Pollution

EX. E.

Title 21—Food and Drugs

CHAPTER II—BUREAU OF NARCOTICS AND DANGEROUS DRUGS, DEPARTMENT OF JUSTICE

PART 308—SCHEDULES OF CONTROLLED SUBSTANCES

Diethylpropion and Phentermine; Temporary Placement in Schedule IV; Interim Regulations

Proposals were published in the FEDERAL REGISTER on May 9 and 10, 1973, proposing placement of benzphetamine (38 FR 12119), chlorphentermine (38 FR 12120), clortermine (38 FR 12121), diethylpropion (38 FR 12230), mazindol (38 FR 12124), phendimetrazine (38 FR 12124), and phentermine (38 FR 12127) in Schedule III of the Controlled Substances Act, and fenfluramine (38 FR 12230) in Schedule IV of the Controlled Substances Act. All interested persons were given until June 7, 1973, to file objections, comments or requests for a hearing. A notice was published in the FEDERAL REGISTER on May 31, 1973, extending the time for filing to June 11, 1973 (38 FR 14288).

On June 15, 1973, a final order was issued placing benzphetamine, chlortermine, clortermine, mazindol, and phendimetrazine in Schedule III of the Controlled Substances Act and fenfluramine in Schedule IV of the Controlled Substances Act (38 FR 15719).

Objections and a request for a hearing were filed on the proposal to control diethylpropion by Merrell National Laboratories, a division of Richardson Merrell Inc., the manufacturer of that substance. Objections and a request for a hearing were filed on the proposal to control phentermine by Pennwalt Corporation, a manufacturer of that substance. The Bureau is currently seeking suitable dates for hearings on these objections.

Until such hearings can be completed, however, the Bureau believes that interim control of diethylpropion and phentermine is desirable. These two substances are reported to be among the most widely prescribed of the non-amphetamine anorectic drugs in the United States. The Bureau's concern that such drugs are likely targets for drug abuse applies with special force to diethylpropion and phentermine because of their wide availability. In addition, in scheduling benzphetamine, clortermine, mazindol and phendimetrazine, the Bureau had indicated to manufacturers that their consenting to control would not be allowed to place them at a competitive disadvantage with other substances being proposed for Schedule III. Without these considerations, the Director requested that Merrell National Laboratories and Pennwalt Corporation consent, respectively, to the placement of diethylpropion and phentermine in Schedule IV of the Controlled Substances Act in the interim before hearings can be held and a final order issued on the proposals to place each substance in Schedule III.

Merrell National Laboratories and Pennwalt Corporation have cooperated with the Director in this request in order to assure that any possibility of abuse of diethylpropion and phentermine during the next weeks is minimized. Both manufacturers have stated, and the Bureau has agreed, that this consent does not constitute an admission to any facts or findings regarding the abuse potential or dependence liability of the two substances, nor a waiver of the right to contest any assertion of fact or law involved in the hearings on placement in Schedule III, nor a withdrawal of the requests for such hearings, nor does it alter the burden of proof on any issue of fact in such hearings. In the same manner this interim action in no way affects the Bureau's proposal that diethylpropion and phentermine be placed in Schedule III. For all parties this interim order represents the most expedient course of action necessary to protect public health and safety, to preserve the rights of the manufacturers of diethylpropion and phentermine, and to observe the legitimate interests of the manufacturers of the other anorectic drugs now controlled.

The Bureau construes that the published proposals to place diethylpropion and phentermine in Schedule III comply with the procedures required by section 201 of the Controlled Substances Act for the placement of these substances in Schedule IV, in this situation. The pertinent regulatory controls on Schedules III and IV are substantially identical. There being no objections to the placement of these substances in Schedule III (other than those of the two manufacturers), it would appear unlikely that anyone would now object to their placement in Schedule IV, except possibly for manufacturers of other anorectic drugs in competition with diethylpropion and phentermine. The Bureau has consulted with these manufacturers and each agreed to this interim action. The USV Pharmaceutical Corporation so agreed on conditions which are acceptable to the Bureau and which will be set forth in a letter to be dated July 2, 1973 from counsel for the Corporation. Therefore, under these unusual circumstances the Director finds that section 201 has been complied with and no further proposal be made but an order issued to place diethylpropion and phentermine in Schedule IV at this time.

DIETHYLPROPION

Based upon the investigations and review of the Bureau of Narcotics and Dangerous Drugs and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education and Welfare, received pursuant to sections 201(a) and (b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a), (b)), the Director of the Bureau of Narcotics and Dangerous Drugs finds that:

1. Based on information now available, diethylpropion has a low potential for abuse relative to the drugs or other substances currently listed in Schedule III.

2. Diethylpropion has a currently accepted medical use in treatment in the United States.

3. Abuse of diethylpropion may lead to limited psychological dependence relative to the drugs or other substances in Schedule III.

The Director has concluded from his review of the current situation that control of all anorectic drugs, including diethylpropion, is desirable at this time to insure that they will not become widely abused. While instances of abuse with diethylpropion are irregular and infrequent, the Director believes that scheduling will prevent diethylpropion from becoming the subject of abuse as amphetamines become increasingly unavailable in the illicit market. In this regard the Bureau recognizes that the manufacturer has presented data indicating that in environments where amphetamines have been banned, diethylpropion has not become the subject of increased abuse. This scheduling will fulfill the congressional mandate to act before substantial problems have arisen. Merrell National Laboratories, a division of Richardson Merrell, Inc., the only manufacturer of diethylpropion in the United States, has participated in conferences with the Bureau and cooperated fully by making available to both the Bureau and the Department of Health, Education and Welfare an extensive analysis of published and unpublished reports of diethylpropion abuse. Upon the conditions set forth in a letter to the Bureau from counsel for Merrell National Laboratories, dated June 29, 1973, to which the Bureau agrees, the manufacturer has consented to the placement of diethylpropion in Schedule IV to insure that it does not become subject to abuse in the period prior to final action on the proposal to place diethylpropion in Schedule III.

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PHENTERMINE

n the investigations and re- Bureau of Narcotics and Drugs and upon the scien- l evaluation and recom- of the Secretary of Health, and Welfare, received pur- 201(a) and (b) of the e Drug Abuse Prevention Act of 1970 (21 U.S.C. , the Director of the Bu- otics and Dangerous Drugs

n information now available, e has a low potential for e to the drugs or other sub- ently listed in Schedule III. ermine has a currently ac- l use in treatment in the ates.

of phentermine may lead to chological dependence rela- ts or other substances in

ector has concluded from his the current situation that con- l anorectic drugs, including ine, is desirable at this time to they will not become widely is scheduling will fulfill the al mandate to act before sub- problems have arisen. The oratories, Division of Sandoz- Inc., one of the two manufac- phentermine in the United has fully cooperated with the and has consented to the place- phentermine in Schedule III to it does not become subject to the future. The Pennwalt Cor- the other manufacturer of ine in the United States, has ed in conferences with the pon the conditions set forth in to the Bureau from counsel for Corporation, dated June 26, which the Bureau agrees, the urer has consented to the t of phentermine in Schedule ure that it does not become abuse in the period prior to ion on the proposal to place ine in Schedule III.

CONCLUSION

fore, under the authority vested Attorney General by section 201 the Comprehensive Drug Abuse

tion and Control Act of 1970 (21 (a)), and delegated to the r of the Bureau of Narcotics and ous Drugs by § 0.100 of Title 28 Code of Federal Regulations, the r orders that § 308.14 of Title 21 Code of Federal Regulations be ed by the addition of a new para- to read:

§ 308.14 Schedule IV.

* * * * *

(d) *Stimulants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Diethylpropion	1610
(2) Phentermine	1640

FUTURE ACTION REGARDING ANORECTICS

Because of the similarities among the substances controlled by this order, and between those substances and the stimulants currently listed in Schedules II and III, the Director is controlling these substances at this time in order to prevent their becoming the subject of abuse as amphetamines become less available in the illicit market through the operation of the Bureau's regulatory controls and criminal enforcement actions. The Director believes that evidence suggests these anorectics may be future targets of stimulant abusers.

The Bureau intends to proceed to hearings on the placement of diethylpropion and phentermine in Schedule III in the near future. The times and places of such hearings will be announced shortly.

The Bureau, over a longer period, will monitor the manufacture, distribution, and use in the United States of diethylpropion and phentermine, as well as those anorectic drugs controlled on June 15, 1973, paying special attention to indicators of diversion (such as shortages in accountability audits of distributors and dispensers, thefts from handlers, and availability on the illicit market) and to other indicators which indicate that any of these substances are actually being abused (such as excessive prescribing and dispensing, reports of adverse reactions and overdoses, and other medical experiences). The Bureau will also consider, if available, clinical and other research in abusability, dependence-creating, and dependence-sustaining characteristics of any of these substances. If, after 18 months during which these drugs are marketed, experience suggests that any of them have not been subject to significant diversion or abuse, the Director will review the necessity and desirability of maintaining it under control and will request from the Secretary of Health, Education, and Welfare a new scientific and medical evaluation, and his recommendation, as to whether that substance should be so controlled or removed as a controlled substance.

Any interested person may petition the Bureau to decontrol any of these substances at any time. If any petition is received to decontrol any one of these substances, or if the Director, based upon the review mentioned above, requests the evaluation and recommendation of the Secretary of Health, Education and Welfare on any of these substances, all of the remaining substances will also be reviewed and, where appropriate, evaluations and recommendations regarding them will also be requested of the Secretary.

Effective dates. The requirements imposed upon the anorectic substances controlled by this order shall become effective as follows:

1. *Registration.* Unless currently registered to conduct that activity with Schedule IV nonnarcotic substances, or unless exempted from registration by law or pursuant to §§ 301.24–301.28 or 311.24–311.28 of Title 21 of the Code of Federal Regulations, any person who manufactures, distributes, dispenses, imports or exports diethylpropion or phentermine or who proposes to engage in the manufacture, distribution, dispensing, importation, or exportation of either of those substances, shall obtain a registration to conduct that activity on or before August 1, 1973.

2. *Security.* Diethylpropion and phentermine must be manufactured, distributed and stored in accordance with §§ 301.71, 301.72(b), 301.73, 301.74, 301.75(b) and 301.76 of Title 21 of the Code of Federal Regulations on or before September 1, 1973. In the event that this poses special hardships, the Bureau will entertain any justified requests for extensions of time.

3. *Labeling and packaging.* All labels on commercial containers of, and all labeling of, diethylpropion and phentermine which are packaged after September 1, 1973, shall comply with the requirements of §§ 302.03–302.05 and 302.08 of Title 21 of the Code of Federal Regulations. In accordance with § 302.06(c) of Title 21 of the Code of Federal Regulations, the Director finds that early compliance with these requirements is necessitated by the fact that early control of these substances has been undertaken to prevent abuse before it becomes widespread; prompt and adequate notice of control is essential to carry out this purpose and thereby protect the public health and safety. In addition, the Director believes it would be unfair and discriminatory to allow any greater period of time between the effective dates of labeling for the anorectics newly approved for marketing and the effective dates for those anorectics which have been marketed for some period of time. In the event these effective dates pose special hardships on any manufacturer, the Bureau will entertain any justified requests for an extension of time.

4. *Inventory.* Every registrant required to keep records who possesses any quantity of diethylpropion or phentermine

shall take an inventory of all stocks of those substances on hand on September 1, 1973.

5. *Records.* All registrants required to keep records pursuant to Part 304 of Title 21 of the Code of Federal Regulations shall maintain such records on diethylpropion and phentermine commencing on the date on which the inventory of those substances is taken.

6. *Prescriptions.* All prescriptions for products containing diethylpropion and phentermine shall comply with §§ 306.01-306.06 and 306.21-306.25 of Title 21 of the Code of Federal Regulations no later than September 1, 1973. Any prescription for any of the foregoing products which was issued before March 1, 1973, or which has been refilled more than five times, may not be refilled after September 1, 1973.

7. *Importation and exportation.* All importation and exportation of diethylpropion and phentermine on and after September 1, 1973, shall be in compliance with Part 312 of Title 21 of the Code of Federal Regulations.

8. *Criminal liability.* Any activity with diethylpropion or phentermine, not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act, conducted after the date this order is published in the FEDERAL REGISTER shall be unlawful, except that any person who is not now registered to handle these substances but who is entitled to registration under those Acts may continue to conduct normal business or professional practice with those substances between the date on which this order is published and the date on which he obtains the proper registration.

9. *Other.* In all other respects, this order is effective on July 6, 1973.

Dated: June 29, 1973.

JOHN E. INGERSOLL,
Director, Bureau of Narcotics and Dangerous Drugs.

[FR Doc.73-13691 Filed 7-5-73;8:45 am]

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA,

-v-

EDWARD PASTOR,
MARTIN WEINER,

Defendants.

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BILL OF PARTICULARS

75 Cr. 753 (C.E.N.)

GOVERNMENT'S BILL OF PARTICULARS

Count One

A. The Government presently knows of no unindicted co-conspirators other than those specified in Count One of the indictment.

B. For the overt acts listed in Count One of the indictment, the time of occurrence, date, and place of occurrence are as follows:

1. The first overt act occurred on or about May 4, 1973 at the Philadelphia, Pennsylvania Airport.

2. The second overt act occurred on or about June 22, 1973 in the vicinity of 33 Union Square West in Manhattan, New York City.

3. The third overt act occurred during a telephone conversation between Martin Weiner and Charles Fernald in or about late June 1973. Charles Fernald spoke on the telephone at 33 Union Square West in Manhattan, New York City.

4. The fourth overt act occurred during a telephone conversation between Martin Weiner and Charles Fernald on or prior to September 13, 1973. Charles Fernald spoke on the telephone at 33 Union Square West in Manhattan, New York City.

5. The fifth overt act occurred during a telephone conversation between Edward Pastor and Charles Fernald in or about November, 1973 and in a letter dated November 23, 1973 received at 33 Union Square West in Manhattan, New York City. During the telephone conversation Charles Fernald spoke on a telephone at

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33 Union Square West in Manhattan, New York City.

6. The sixth overt act occurred on or about November 23, 1975.

7. The seventh overt act occurred in or about 1973 at the APA Transport terminal in Philadelphia, Pennsylvania. (Several times during 1973 and 1974 Edward Pastor told APA Transport employees, in face-to-face conversations and during telephone conversations, that Pastor was Dr. Horace Johnson. The seventh overt act is the first such face-to-face representation.)

8. The eighth overt act occurred during a telephone conversation between Edward Pastor and Charles Fernald in or about the middle of April 1974, and in a letter mailed in Philadelphia, Pennsylvania on April 18, 1974 and received threafter at 33 Union Square West in Manhattan, New York City. Charles Fernald spoke on the telephone at 33 Union Square West in Manhattan, New York City.

9. The ninth overt act occurred on or about April 18, 1974.

Count Two

A. The misrepresentation, fraud, deception and subterfuge charged in Count Two of the indictment occurred on or prior to July 26, 1973 during a telephone conversation between Edward Pastor and Charles Fernald, when Edward Pastor ordered 100,000 phendimetrazine tablets for Dr. Horace Johnson. Charles Fernald spoke on the telephone at 33 Union Square West in Manhattan, New York City.

Count Three

A. The misrepresentation, fraud, deception and subterfuge charged in Count Three of the indictment occurred on or about September 13, 1973 during a telephone conversation between Edward Pastor and Charles Fernald, when Edward Pastor ordered 250,000 phendimetrazine tablets for Dr. Horace Johnson.

Charles Fernald spoke on the telephone at 33 Union Square West in Manhattan, New York City.

Count Four

A. The misrepresentation, fraud, deception and subterfuge charged in Count Four of the indictment occurred in or about November 1973 during a telephone conversation between Edward Pastor and Charles Fernald, when Edward Pastor ordered 2,000,000 phendimetrazine tablets for Dr. Horace Johnson; during a subsequent telephone conversation in November 1973 between Edward Pastor and Charles Fernald, when Edward Pastor said that Wingate Sales would receive the order on the letterhead of a doctor with a valid BNDD (i.e., Bureau of Narcotics and Dangerous Drugs) number; in a letter, dated November 23, 1973 and received at 33 Union Square West in Manhattan, New York City, that purported to be signed by Dr. Horace Johnson, to be on Dr. Johnson's letterhead, and to verify an order for 2,000,000 phendimetrazine tablets; and during a subsequent telephone conversation in November 1973 between Edward Pastor and Charles Fernald when Pastor said that the November 23, 1973 letter contained a typographical error. During the telephone conversations enumerated in this particular Charles Fernald spoke on a telephone at 33 Union Square West in Manhattan, New York City.

Count Five

A. The misrepresentation, fraud, deception and subterfuge charged in Count Five on the indictment occurred in or about April 1974 during a telephone conversation between Edward Pastor and Charles Fernald, when Edward Pastor ordered 1,000,000 phendimetrazine tablets from Dr. Horace Johnson, and in a subsequent letter postmarked April 18, 1974 and received

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thereafter at 33 Union Square West in Manhattan, New York City, that purported to be signed by Dr. Horace Johnson, to be on Dr. Johnson's letterhead, and to order 1,000,000 phentermine tablets. During the telephone conversation Charles Fernald spoke on a telephone at 33 Union Square West in Manhattan, New York City.

Yours, etc.

THOMAS J. CAHILL
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Southern District of New York
Attorney for the United States
of America

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

- - - - - - - - - - - - - - - - - - x

UNITED STATES OF AMERICA : SUPPLEMENTAL BILL OF PARTICULARS

-v- :

EDWARD PASTOR and MARTIN WEINER, :

Defendants. :

- - - - - - - - - - - - - - - - - - x

GOVERNMENT'S SUPPLEMENTAL BILL OF PARTICULARS

A. In addition to the unindicted co-conspirators specified in Count One of the indictment, the Government charges that the following persons are unindicted co-conspirators:

Ira Sacha, President, Danbury Pharmacal, Inc.

Saul Green, formerly, salesman, Garden Laboratories, Inc.

B. Paragraphs 6 and 7 of the Government's Bill of Particulars are amended to read, as follows:

6. The sixth overt act occurred on or about November 23, 1973.

7. The seventh overt act occurred in or about 1974 at the APA Transport terminal in Philadelphia, Pennsylvania. (Several times during 1974 Edward Pastor told APA Transport employees, in face-to-face conversations and during telephone conversations, that Pastor was Dr. Horace Johnson. The seventh overt act is the first such face-to-face representation.)

Count Three (in superseding indictment)

A. The misrepresentation, fraud, deception and subterfuge charged in Count Three of the indictment occurred in or about the end of July and the beginning of August in 1973, including long distance telephone calls between Charles

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Fernald and the residence of Edward Pastor on August 12 and 21, 1973 and one or more meetings between Charles Fernald and a defendant, or the defendants, in Philadelphia, Pennsylvania. During the telephone conversations Charles Fernald spoke on a telephone at 33 Union Square West in Manhattan, New York City.

Defendants' Demands for Particulars that the Court has Directed the Government to Answer

A. The B.N.D D. registration number utilized by the defendants was AJ 4828743. This registration number was assigned to Dr. Horace Johnson. The number was not suspended. It expired on, or prior to, December 31, 1972, when no application to renew was filed. (Defendants also utilized Dr. Horace Johnson's Pennsylvania registration number 16069.)

(Defendants' Demand 6(D)(2))

B. Most documents in the Government's custody or control that are requested in defendants' demand 6(D)(6) have already been produced to the defendants in the course of discovery, pursuant to Rule 16 of the Federal Rules of Criminal Procedure. (Some additional documents are annexed hereto.

(Defendants' Demand 6(D)(6))

C. All documents in the Government's custody or control that relate to the acts alleged in overt acts numbered 5, 6 and 8 have already been produced to the defendants, pursuant to Rule 16 of the Federal Rules of Criminal Procedure.

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(Defendants' demands 6(D)(12), 6(D)(13), and 6(D)(15).)

Yours, etc.

THOMAS J. CAHILL
United States Attorney for the
Southern District of New York
Attorney for the United States
of America

By: _____
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Attorney for Defendant Martin Weiner

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----------x

UNITED STATES OF AMERICA :

:

-against- :

:

EDWARD PASTOR and MARTIN WEINER, : 76 CR. 2

:

Defendants. :

:

APPEARANCES

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CONSTANCE BAKER MOTLEY, D. J.

MEMORANDUM OPINION

By motion filed with the court on January 5, 1976, defendant Edward Pastor requested an order "[p]ursuant to United States v. Knohl, 379 F.2d 427, 434-37 (2d Cir.), cert. den. 389 U.S. 973, 19 L.Ed.2d 465 (1967), appointing a physician or physicians to examine the defendant, EDWARD PASTOR, to advise the court and counsel with regard to continuing the trial of the instant indictment as to the said defendant until such time as a trial of that indictment will not present a danger to said defendant's health or will not endanger the said defendant's life, and until such time as the said defendant will be able to properly assist in his own defense, or ordering a hearing concerning such continuance." This request was based upon Mr. Pastor's history of a serious heart condition which had previously been documented by a letter from Dr. Gaddo Onesti, Professor of Medicine at the Hahnemann Medical College & Hospital of Philadelphia, who had previously treated Mr. Pastor. (A copy of that letter is annexed hereto as Appendix A.)

The Government consented both to an examination of Mr. Pastor and to a hearing to determine his physical ability to stand trial. Accordingly, he was examined on February 10, 1976 by Dr. Leslie A. Kuhn, a physician whom he designated, and a copy of Dr. Kuhn's report (annexed hereto as Appendix B) was submitted to the court. On February 11, Mr. Pastor

was examined by Dr. Meyer Texon, a physician selected by the Government, and his report (annexed hereto as Appendix C) was submitted to the court.

The reports of Drs. Kuhn and Texon differed somewhat in their diagnoses of Mr. Pastor's heart disease, but more significantly in their assessments of the possible and probable effects on his health of the stress of participation in a criminal trial. In view of this discrepancy, the court ordered that a hearing be held on February 17, with Mr. Pastor present, to afford both the Government and defense counsel the opportunity to present the testimony of their experts and to test the analysis of their adversary's by cross-examination. Moreover, the Government sought to question Mr. Pastor concerning the scope of his recent activities which could bear upon his ability to withstand stress and to engage in light physical activity. However, Mr. Pastor failed to appear on February 17 since he was hospitalized in Philadelphia on the preceding day, February 16. Despite Mr. Pastor's absence, the court heard a full day of testimony from Dr. Kuhn and Dr. Texon on February 17 concerning the nature and extent of Mr. Pastor's heart condition. (See transcript of hearing.)

Since neither physician had examined Mr. Pastor subsequent to his hospitalization, their testimony was directed primarily to an analysis of his chronic condition,

its prognosis, and its implications as to his ability to withstand the stress of a courtroom setting.

Thereafter, Dr. Texon reexamined Mr. Pastor at the Hahnemann Hospital in Philadelphia on February 21, and submitted his report to the court. (A copy of that report is annexed hereto as Appendix D.) Dr. Texon confirmed that Mr. Pastor had, in fact, suffered an attack of congestive heart failure, and recommended that Mr. Pastor remain hospitalized for an additional seven to ten days. Mr. Pastor's own doctor, Gaddo Onesti, in an affidavit dated February 18, 1976 stated as follows: "At this time, the duration of the hospitalization in the Coronary Care Unit and in the Hahnemann Hospital cannot be determined. It is estimated that it will not be less than two weeks. His convalescence period, confinement to the house, is estimated to be approximately two-three months." (Copy of affidavit attached as Appendix D-1.) After considering the Onesti affidavit and Dr. Texon's report of February 21, 1976, the court adjourned the trial until May 17, 1976. Mr. Pastor left the hospital on March 1, 1976.

By letter dated March 4, 1976 (attached hereto as Appendix D-2), Mr. Pastor's counsel stipulated as follows concerning the probable period required for his recovery: "Acting for Edward Pastor, we stipulate that the recuperative period required by the congestive heart failure for which Mr. Pastor was hospitalized on February 16, 1976 should not predictably extend past May 17, 1976. We further agree, as Mr. Pastor's lawyers, that no contrary claim will be made by us."

On April 19, 1976 Mr. Pastor moved again for continuance of his trial on the ground that standing trial would endanger his life and health. Pursuant thereto, the court again directed that Mr. Pastor be examined by Dr. Kuhn, the expert of his own choice, and Dr. Texon, the Government's expert.

Mr. Pastor was reexamined by Dr. Texon at his home in Philadelphia on May 9, 1976, and a copy of his report (annexed hereto as Appendix E) was submitted to the court. In significant part, Dr. Texon noted the following: "It is notable that this patient now presents no evidence of congestive heart failure. His lungs are clear. He is able to ambulate at will in his own home and there is no evidence that infarction or tachy-arrhythmia has appeared at any time since he has been observed during the past ten years. The anginal pains are relatively stable and appear controlled with Nitrol ointment or Nitroglycerin. Other medications are taken as advised with apparent clinical stabilization of the cardiac status. . . . The total cardiac status appears to be improved compared to the status on 2/21/76. In my opinion, this patient has coronary occlusive atherosclerosis and a healed myocardial infarction. I believe his cardiac reserve may be considered diminished but is presently adequate to allow him to be up and about, to travel by automobile, and to participate in a court proceeding.... Although this patient may experience chest pain in a court proceeding, I believe it is very unlikely and only remotely possible that a myocardial infarction will occur as a result of his antecedent atherosclerosis at precisely the time of his participating in a court proceeding. Further clinical manifestations of the patient's heart disease such as tachycardia or

pulmonary congestion are possible—but these, in my opinion, can be successfully controlled as in the past and constitute no serious risk or hazard to the patient's health or life in view of the relatively good cardiac status of the patient at this time."

Mr. Pastor was subsequently reexamined by Dr. Kuhn on May 11 and a copy of this report (annexed hereto as Appendix F) was submitted to the court. Dr. Kuhn's report concluded as follows: "Because of the underlying severe triple vessel coronary artery disease, the episodes of severe and prolonged myocardial ischemia with relatively slight provocation by emotional tension or modest activity, it is likely that participation in his trial with its physicial [sic] and emotional stresses would be a risk to his health and might have life threatening consequences."

The court has determined, on the basis of the testimony adduced at the February 17 hearing and the reports annexed hereto that a further hearing at this time is unnecessary. The issue raised by Dr. Kuhn's report was thoroughly heard on February 17, 1976.

The court finds, based on all the evidence, that Mr. Pastor is able to withstand the stress of participation in a criminal trial, and to assist in his own defense, without grave risk to his life or health.

It is true that Dr. Kuhn has consistently assessed the risk of such participation somewhat more severely than has Dr. Texon, indicating after each of his examinations that participation at trial would pose a "definite risk to his health and might have life threatening consequences." However, in his reports, Dr. Texon has equally consistently asserted his conclusion that the likely result of standing trial would be primarily an increase in chest pain occasioned by tension which could be effectively controlled by medication.

In view of the foregoing, the trial will proceed for four hours per day, with such recesses as are required to enable Mr. Pastor to rest outside the courtroom and to receive medication. Mr. Pastor will be examined by Dr. Texon every two days to ensure that his health is not being seriously affected by his presence at trial. Mr. Pastor's doctor may also be present during such examination or conduct his own independent examination periodically throughout the trial. At this time, the presence of a registered nurse in the building and the proximity of the courthouse to the Beekman Downtown Hospital seem adequate to ensure the ready availability of emergency medical treatment for the defendant, should that unfortunate necessity arise. If, in the course of the trial, it should appear wise to have medical assistance more

immediately at hand, then alternative arrangements will be considered at that time.

Dated: New York, New York
May 14, 1976

CONSTANCE BAKER MOTLEY
U. S. D. J.

THE HAHNEMANN MEDICAL COLLEGE & HOSPITAL OF PHILADELPHIA
TWO-THIRTY NORTH BROAD STREET PHILADELPHIA, PENNSYLVANIA 19102

DIVISION OF HEMATOLOGY AND HEMATOPOIESIS

September 25, 1975

Mr. Richard H. Kuh
Kuh, Shapiro, Goldman, Cooperman, and Levitt
800 Third Avenue
New York, New York 10022

Dear Mr. Kuh:

Mr. Edward Pastor was hospitalized at Hahnemann Hospital from March 19, 1966 to April 30, 1966 for an acute myocardial infarction.

He sustained a second attack on July 5, 1966.

Following these two episodes, he was put on long-term anticoagulant therapy and coronary dilators. Recurrent episodes of angina continued.

From March 22, 1967 to April 6, 1967, he was hospitalized at the Pennsylvania Hospital for another myocardial infarction.

Since that time, he continued to have symptoms of coronary insufficiency.

During the years, 1973-1974, angina attacks continued and became more severe.

On October 2, 1974, he was hospitalized again at the Hahnemann Hospital for crescendo angina and impending myocardial infarction. It was our opinion that although the angina was severe, no infarction had occurred at that time.

After discharge, it became evident that Mr. Pastor was developing essential hypertension with hypertensive cardiovascular disease, and he was treated with diuretic and propranolol.

APPENDIX "A"

During the month of September, 1975, his precordial pain increased and was present both at rest and during exercise.

On September 11, 1975, Mr. Pastor was hospitalized at the Hahnemann Hospital again as an emergency, because of unstable crescendo coronary insufficiency. He was admitted to the coronary care unit. Serial electrocardiograms revealed severe coronary artery disease.

Cardiac catheterization was performed which demonstrated a complete occlusion of the right coronary artery. In addition, there was an occlusion of the left coronary artery with the lower segment of it vascularized by collateral circulation. There was evidence of severe damage to the left ventricle with hypokinetic ventricular contractions.

The diagnosis at this time is advanced, irreversible coronary artery disease, with crescendo angina and impending myocardial infarction with severe myocardial insufficiency.

The patient has been put at limited activity and heart surgery is considered within the next 4-5 months if the clinical picture stabilizes. The prognosis is extremely serious.

If there are any questions, or if I can be of any further help, please do not hesitate to contact me.

Sincerely yours,

Gaddo Onesti

Gaddo Onesti, M.D.
Professor of Medicine
Department of Medicine

GO:rr

LESLIE A. KUHN, M.D., P.C.
THE MOUNT SINAI HOSPITAL
1176 FIFTH AVENUE
NEW YORK, N. Y. 10029

TELEPHONE (212) TRAFALGAR 6-9009

288a

February 11, 1976

Mr. Andrew R. Cooper
Kuh, Shapiro, Goldman
Cooperman and Levitt
800 Third Avenue
New York, N. Y. 10022

Dear Mr. Cooper:

I have examined the hospital records, the letters of Dr. Onesti and Dr. Makous, concerning Mr. Edward Pastor. I have analyzed the angiocardiograms performed at Hahnemann Hospital in Philadelphia on September 16, 1975 and have reviewed these with an expert in cardiac radiology, Dr. Murray Baron, Associate Professor of Radiology at Mount Sinai School of Medicine. On February 10, 1976, I had the opportunity of questioning and examining Mr. Pastor in my office.

Mr. Pastor was well until 1966 when he sustained acute myocardial infarction. His course since has been characterized by recurrent episodes of myocardial ischemia with prolonged severe chest pain necessitating hospitalization in 1966, March, 1967, and in July, 1968. Further hospitalization was required in 1970 and in 1974 for additional episodes of severe myocardial ischemia. For the last three years, there have been frequent episodes of angina pectoris on slight activity or with emotional tension. These are characterized by left anterior chest tightening and radiation of the pain to the left arm. The symptoms worsened considerably in September, 1975, and he was hospitalized at Hahnemann Hospital. An angiocardiogram was performed on September 16, 1975. The report has been forwarded to you and, as indicated, I have had the opportunity of reviewing the films in detail. These show extensive obstructive coronary artery disease involving all three major coronary arteries with total occlusions of the left anterior descending coronary artery and the right coronary artery and about a 90% occlusion of a major branch of the left circumflex coronary artery. Since his discharge from the hospital, Mr. Pastor has had severe angina with his nitroglycerine requirement increasing up to twenty tablets per day depending on the level of his

activity and his emotional tension. These episodes of angina are precipitated by slight activity, particularly in the cold, as well as by emotional tension. He has had nocturnal attacks during the past few weeks. His physical activity has been severely restricted despite Inderal, 40 mg., 4 times daily, Sublingual Isordil, 5 mg., 4 times daily with supplementary doses as necessary, Atromid S, 500 mg., 4 times daily (for hyperlipidemia), meprobamate 400 mg. and Librium 25 mg. for sleep as well as phenobarbital, grains one, 3 times daily. Apparently even slight degrees of emotional tension are enough to precipitate anginal episodes. A more prolonged bout, lasting about one hour, was noted about a week prior to my seeing him.

There is a strong familial history of coronary artery disease with his father and brother dying at the age of forty-seven years of a heart attack and one brother sustaining a heart attack at the age of thirty years. He is known to have had high blood fats and hypertension in the past and also has a past history of phlebitis of the leg in 1973.

On physical examination, he was well developed. He required frequent nitroglycerine tablets during the period of questioning and examination. The blood pressure was 160/110 (right arm-supine). The pulse was 68 and regular. The weight was 180 1/2. There was no venous distention or hepatojugular reflux. The thyroid was not felt. The trachea was in the mid line. The lungs were clear. The point of maximal impulse of the heart was not felt. There was regular sinus rhythm. There were no thrills or murmurs. There was a 4th heart sound at the apex. The basal sounds were normal. The abdomen was normal. The femoral and pedal pulses were equal. There was no edema nor calf tenderness.

The chest x-ray revealed the cardiac silhouette to be at the upper limit of normal. The aorta was tortuous. The lung vascular markings were slightly increased. Cardiac fluoroscopy showed some diminution of the pulsations at the apical and inferior borders of the heart. The electrocardiogram, portions of which are enclosed, showed regular sinus rhythm. There was a Q wave in leads III and AVF and an inverted T in lead III, indicating a previous inferior myocardial infarction.

The findings are those of hypertensive and arteriosclerotic heart disease of severe degree with previous myocardial infarction and recurrent episodes of myocardial ischemia. There is evidence of advanced angina pectoris with symptoms of myocardial ischemia on

slight activity or with relatively slight emotional tension. The anginal complaints have recently accentuated in frequency and severity and now they occur nocturnally as well as during the day. There is evidence of extensive obstructive coronary artery disease with all three major coronary arteries involved to a considerable degree. Because of the extent of the underlying coronary artery disease and because Mr. Pastor's angina pectoris is severe and somewhat unstable at this time, his participation in a trial with its attendant emotional tension must represent an increased risk to him. This is because it can reasonably be expected that the oxygen needs of his heart will increase during periods of anxiety and emotional tension. Since the arterial supply to his heart muscle is severely compromised, episodes of myocardial ischemia with its attendant complications of angina pectoris, serious arrhythmias, or myocardial infarction may well occur. Therefore, in view of the increasing severity of his symptoms and the established underlying severe coronary artery disease, I believe that his participation in his trial at this time would pose a definite risk to his health and might have life threatening consequences. It is not possible to precisely quantitate the degree of risk faced, but I believe it to be substantial.

Sincerely yours,

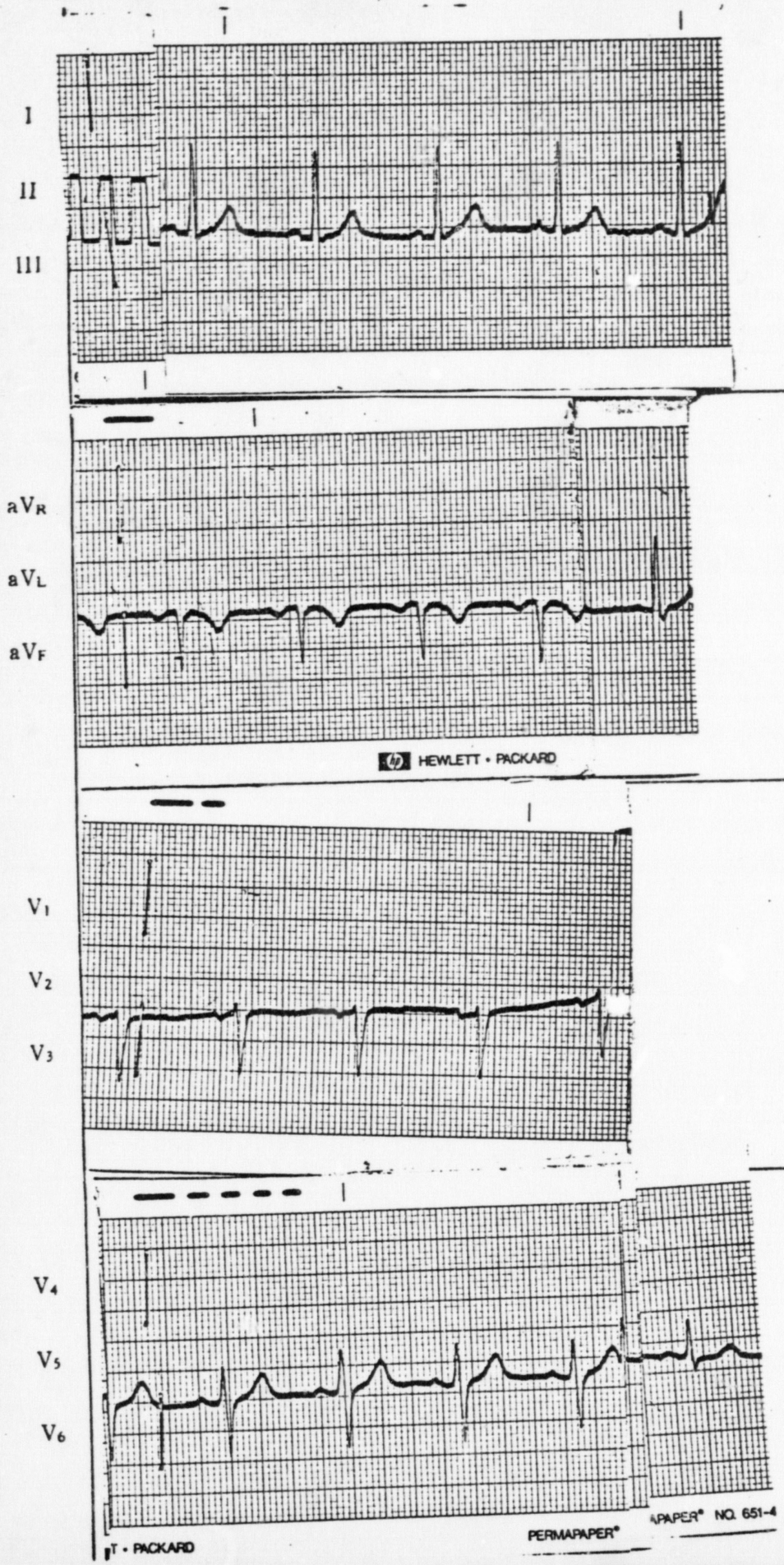
Leslie A. Kuhn, M. D.
Director, Ames Coronary Care Unit
Associate Clinical Professor of Medicine

LAK:sb

LESLIE A. KUHN, M. D.
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1176 FIFTH AVENUE
NEW YORK, N. Y. 10029
TRAFALGAR 6-9009

Patient Edward Pastor

291a Date 2/10/76

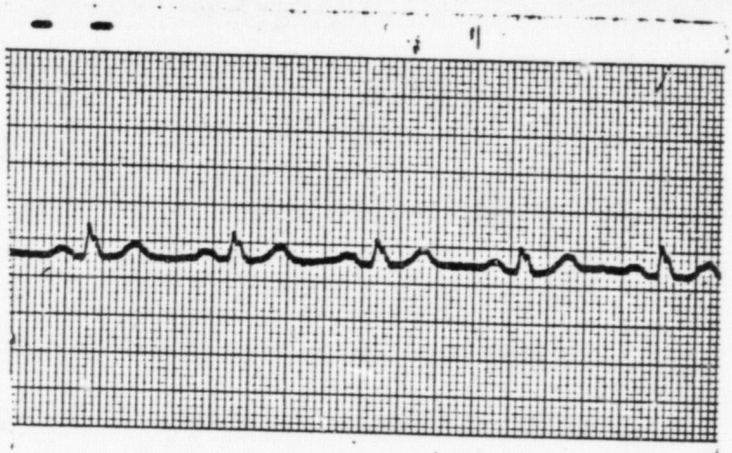


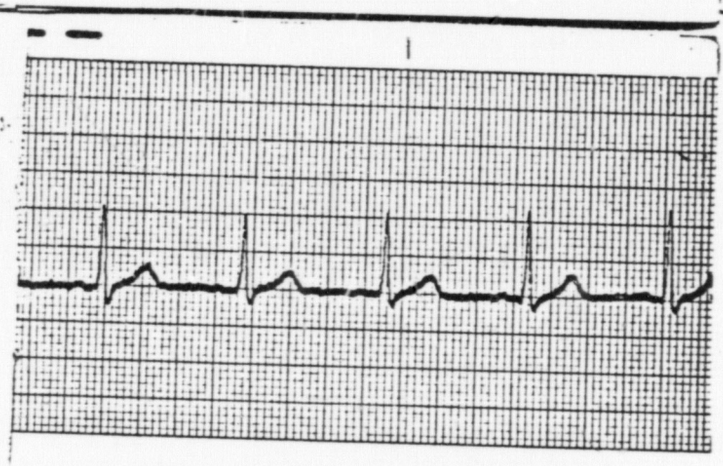
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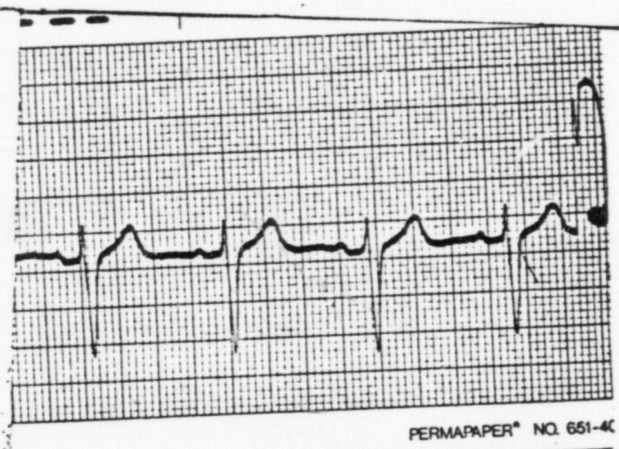
Patient Edward Pastor

Date 2/10/76

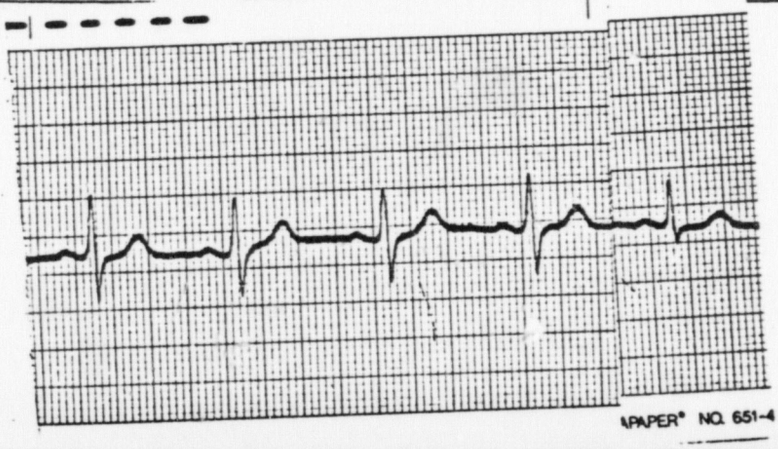
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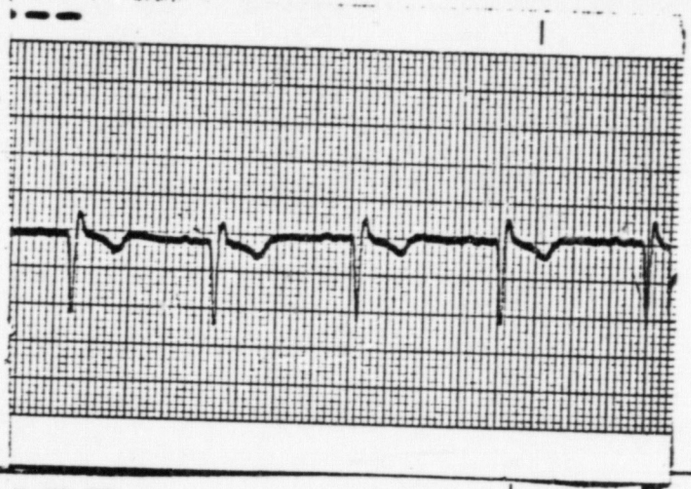
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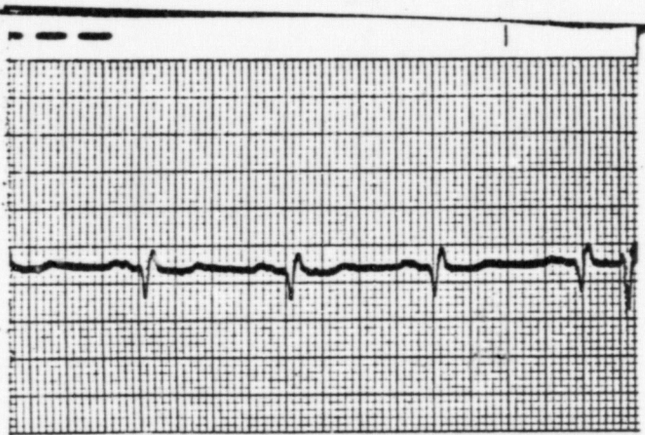
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Patient Edward Pastor

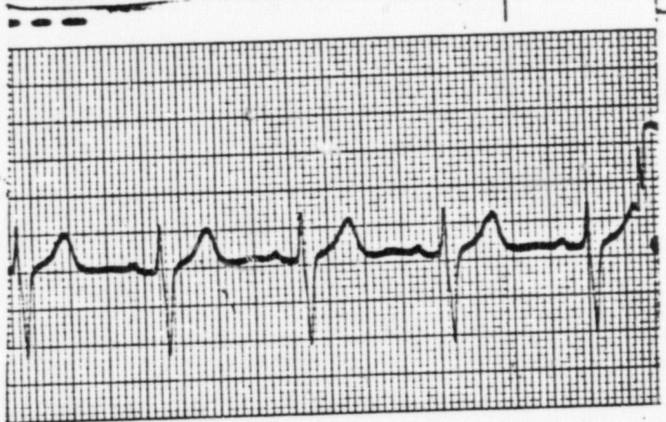
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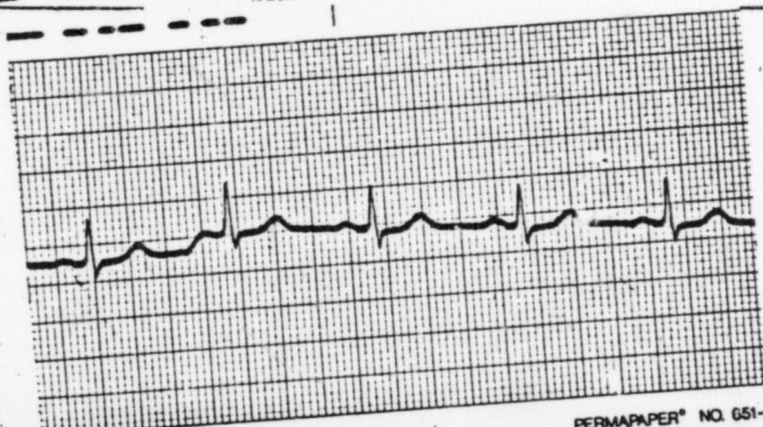
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Leslie A. Kuhn, M. D.

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Consulting Cardiologist, U. S. Veterans Administration Hospital, Bronx, N. Y.
Senior Assistant Editor, American Journal of Cardiology; Editorial Board, N. Y. State Journal of Medicine

Diplomate, American Board of Internal Medicine
Diplomate, Subspecialty Board of Cardiovascular Disease
Fellow, American College of Cardiology
Author of approximately sixty articles on coronary artery disease and myocardial infarction.

Ex B - Govt
2/17/76

MEYER FENSTER, M. D.
3 EAST 80TH STREET
NEW YORK 21, N. Y.

P 295 a

February 12, 1976

Constance Baker Motley
United States District Judge
Southern District of New York
United States Court House
Foley Square
New York, N. Y. 10007

Re: United States vs
Edward Pastor
75 CR 753

Dear Judge Motley:

The following are pertinent medical data contained in the file of the above named submitted for review together with my findings and opinion after examining the patient on February 11, 1976 at my office pursuant to your order dated February 10, 1976:

I REVIEW OF FILE

A) HAHNEMANN MEDICAL COLLEGE HOSPITAL
Edward Pastor
Admitted 3/19/66 - Discharged 4/30/66
Final Diagnosis: Acute myocardial infarction.

B) HAHNEMANN MEDICAL COLLEGE HOSPITAL
Admitted 7/6/66 - Discharged 7/16/66.
Final Diagnosis: 1) Coronary heart disease
2) Acute myocardial ischemia.

C) Letter dated 5/1/67 from Dr. N. Makous to Dr. Onesti
Pennsylvania Hospital.
Admitted 3/22/67 - Discharged 4/5/67.
.....He was received with severe precordial pain and collapsed while in question of Federal Agents, late in the morning on the day of admission. He stated that the chest pain persisted until 3 o'clock in the morning following admission. The pain was similar in type but less severe than that experience of a myocardial infarction last year. Physical Examination: ....chest was clear - heart regular at 96 per minute. Tones distant with suggestion of a middiastolic gallop beat in the mid precordial area. No murmurs. Enzymes on four occasions were all normal. Ekg. showed evidence of previous myocardial infarction. - no remarkable change from previous tracing....taken on 12/15/66. The hospital course was not remarkable.
BP 160/116 - 120/80 - treatment: Coumadin, Phenobarbital....
(no final diagnosis given).

D) HAHNEMANN MEDICAL COLLEGE HOSPITAL
Admitted 6/8/68 - Discharged 6/20/68.
Final Diagnosis: 1) Coronary artery disease
2) Coronary insufficiency.

E) HAHNEMANN MEDICAL COLLEGE HOSPITAL
Admitted: 9/19/72 - Discharged: 9/29/72.
Final Diagnosis: 1) Deep and superficial thrombophlebitis, left leg.
2) Diabetes mellitus.
3) Coronary heart disease.

F) HAHNEMANN MEDICAL COLLEGE HOSPITAL
Admitted: 10/2/74 - Discharged: 10/12/74.
Final Diagnosis: 1) Coronary insufficiency.
2) Hypertension
3) Hyperlipidemia.

Hospital Course: The patient had essentially one major problem - this was chest pain. He was admitted to the coronary intensive care unit to rule out myocardial infarction. The pain dissipated after one or two doses of Demerol in the coronary care unit and not longer recurred. The patient had repeat tracings and repeat enzymes which were all unremarkable....gradually ambulated. At discharge on 11th hospital day, he had no pain."

G) HAHNEMANN MEDICAL COLLEGE HOSPITAL
Admitted: 9/11/75 - Discharged: 9/20/75.
Admitting Diagnosis: Coronary insufficiency.
Final Diagnosis: Severe triple vessel disease of coronary arteries.
Procedure: Cardiac catheterization.
Condition on Discharge: Good.
Final recommendations: Medications: Diazide, Atromid-S, Inderal, Isordil, 2 gram sodium diet. Changed his life style to complete rest. Classified as a stage 4 coronary artery disease.

Present Illness: 50-year-old white male with severe coronary artery disease - having myocardial infarction at Hahnemann in 1966 and again in 1967 and he was hospitalized with a myocardial infarction in Pennsylvania Hospital in 1968. He was noted to be hypertensive.... He has had multiple episodes of acute coronary insufficiency. This did not turn out to be a myocardial infarction. He has had increasing angina. This is typical angina described as classical angina, over the last three weeks. Has increasing frequency over the last (one) week before admission."....
Physical Examination: - well developed, well nourished, white male resting comfortably in bed with BP 160/100 and the rest of his vital signs being within normal limits. Head, eyes, ears, nose, throat, and neck within normal limits. Lungs clear to auscultation and percussion. Heart revealed regular sinus rhythm with an S-4 gallop intermittently and no murmurs or rubs. Abdomen, extremities, and

neurological systems were within normal limits.

Laboratory Data: Ekg. prior to admission showed Q waves in 2,3,F, from an old inferior wall myocardial infarction.
Hospital Course: Admitted to Coronary Intensive Care Unit where he was treated as having an acute myocardial infarction. Ekgs. and enzymes remained stable and were within normal limits. The patient was moved to the floor. Subsequently, due to debilitating nature of his angina, the patient was sent to the cardiac catheterization, to see if the patient had a lesion that could possibly be helped.

Other laboratory studies: Chest X-ray revealed no congestive failure, infiltrate and heart was within normal limits. Ekg. revealed old inferior wall myocardial infarction with nonspecific ST-T wave changes.

Echocardiogram revealed a hypokinetic septal and posterior lateral wall motion which reduced the ejection fraction. Phonocardiogram.... consistent with left ventricular dysfunction. Electrolytes, BUN, Creatinine, SMA-12 - Coagulation studies and Hemogram, urine and VDRL all within normal limits or negative. Lipid profile revealed type IV and type IIB hyperlipidemia.

Catheterization revealed:
1) Normal resting hemodynamics.
2) Left ventricular mild enlargement....
3) The left main coronary artery is free of disease.
3a) Total occlusion of LAD distal to first major septal and diagonal vessels. Distal vessels fill from right and left. Collateral is of normal caliber and free of disease.
3b) Left circumflex reveals 50% narrowing of proximal portion and total occlusion of mid portion of the largest marginal branch.
3c) Right coronary totally occluded with the proximal portion being involved. The distal vessel was filled from right and left.... There are right to right collaterals and left to left collaterals - right to left and left to right collaterals. The patient also had a dominant right coronary artery.

The possibility of surgery was discussed with the patient and in view of severe left ventricular dyskinesia the patient was advised against surgery and also to change his life style....surgical consultants agreed that the patient would be an extremely high risk as surgical candidate in the level of 15 to 20%. The patient was discharged without complications. (Dr. Richard Orose)

9/11/75: 60-year-old white male known to MMCH since 1966 - chest pain diagnosed as myocardial infarction at MMCH in 1966, again in 1967 - had myocardial infarction while at Pennsylvania Hospital. Hypertension found in 1968.
Episodes of coronary insufficiency in 1970 and 1972 and 1974 for which hospitalized at MMCH. He had infrequent episodes of chest discomfort lasting few minutes relieved by Nitroglycerin.

Since Monday (9/8/75) has had several bouts of precordial chest pain needing to take up to 20 Nitroglycerin for relief. Chest discomfort was associated with shortness of breath and diaphoresis.....

9/11/75...."Anginal pattern (2-3 attacks with exertion per week) with slight increase over the past year. He was walking three days prior to admission when he noted episodes of substernal pressure with dyspnea (30 minutes) requiring ten Isordil - relief by rest and Isordil but he continued to walk and rest as necessary at home. At night after a meal he had another bout of pain....over the next two days pain free except with showering each morning, requiring Isordil. Denies palpitation, dyspnea on exertion, paroxysmal nocturnal dyspnea, ankle edema other than as described....
Physical Examination: ....lungs clear... Ekg: no acute changes - (old inferior wall myocardial infarction)

9/12/75: 57-year-old male with progressive angina and dyspnea on exertion - no acute changes on Ekg.

9/12/75: BP 160/120 - no chest pain - monitor normal sinus rhythm - sinus tachycardia - afebrile.

9/13/75: No complaint of chest pain. Ekg. and enzymes no change for three days.

Remains stable - no pain - regular sinus rhythm.

9/13/75: Monitor normal sinus rhythm - no complaints. Out of bed to commode - for transfer off floor.

9/15/75: No chest pain last night. BP 145/102. No acute changes in Ekg., since admission.

9/16/75: Post catheterization note: patient did well.
Tentative diagnosis: Coronary artery disease - severe - three vessel. LAD and right coronary artery totally occluded. Left circumflex severe disease. (Dr. Fox)

9/17/75: BP 130/90. Patient has no complaints.

9/19/75: BP 130/90 and stable for last few days.

H) 9/27/75 - Letter to Mr. R. H. Kuh from Dr. Gaddo Onesti.
"....the diagnosis at this time is advanced irreversible coronary artery disease with crescendo angina and impending myocardial infarction with severe myocardial insufficiency."
The patient has been put at limited activity and heart surgery is considered within the next four to five months if the clinical picture stabilizes. The prognosis is extremely serious."

I) 11/6/75 - Letter to Mr. R. H. Kuh from Dr. Gaddo Onesti
"Since October, 1972, Mr. Pastor has received daily treatment with 1) Propanolol 2) Dyazide 3) Isordil 4) Librium 5) Phenobarbital 6) Clofibrate 7) Miltown.
....some of these drugs used alone, but particularly when used in combination, result very frequently in loss of mental alertness, drowziness, disorientation and mental confusion."......

J) 2/9/76 - Letter signed by Dr. G. Onesti
"On Monday, 2/9/76, I re-examined Mr. Edward Pastor for his routine follow-up.
"Mr. Pastor related episodes of severe substernal and precordial pain 5 to 6 times a day after minimal exercise and after stressful conversations.
In past ten days - nocturnal angina has appeared every night, associated with dreams.
Physical examination: BP 140/100 supine, 130/105 standing.
Neck veins not distended. Carotid pulses normal. Lungs clear - heart sounds distant - rate 62 per minute, regular, no murmurs.
Liver and spleen normal. No peripheral edema.
In summary, there is severe exacerbation of the angina, which occurs now even at night.
Treatment: Inderal, Isordil, Atromid, Meprobamate, Phenobarbital."...

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****

This 57-year-old pharmacist gives the following account of his illness:
History: I have the following complaints:
1) Pain in the chest - This Pain is vise-like or squeezing in character located midsternally, it radiates to the left mid arm area. I take Isordil 5 mg. under the tongue and Nitroglycerin 2, 1/150 grain tablet - immediately and the pain subsides after 4 to 5 minutes. If I am at home or in a location where I can rest, some of the episodes of pain may subside by resting without need for Nitroglycerin.

The pattern of pain since September, 1975 has been relatively unchanged. If I am at home resting, away from my business tensions, there may be two or three days per week when I have no pain at all and I have no need for Nitroglycerin. On the other 4 or 5 days in the week I have from 8 to 10 episodes on the average of pain and require Nitroglycerin. In the past 4 nights I have been awakened by chest pain requiring Nitroglycerin. This occurs (pain at night) about once in two or three weeks.

I have no chest pain when walking about in my own apartment at home. I don't become short of breath if I stay indoors at home.

Outdoors on a nice day without wind I can walk about ½ block at a normal pace. If I walk on a cold day (below 32 degrees) or in the wind, I get chest pain immediately. If there is no wind and the temperature is about 50 degrees I can walk about ½ to one block.

Sex relations require me to take Nitroglycerin prior to engaging. This occurs about twice a month.

Emotional stress also produces chest pain - in the mid chest, and this responds to Nitroglycerin. Examples of emotional stress or anxiety are talking to manufacturers about drug prices - anxiety about improper performance of duty in my business and the running of the business. I act as consultant in my business and my wife is the manager of the firm. Talking about my legal problems also produces mid chest pain, relieved by Nitroglycerin.

I also have a second type of chest pain - located to the left of the midline in the chest which occurs three or four times a week and may last for several hours. This is of a dull character and does not respond to Nitroglycerin. It may occur at rest, or with effort, even while lying down. The pain subsides gradually with no medication. This second type of pain also began in September, 1975 (4 to 5 months ago).

These two types of pain are not associated with rapid heart action (palpitation), faintness, sweating or shortness of breath.

2) Fatigue - I feel fatigued easily whether I am talking or walking. This is both an emotional and physical fatigue. I must take a nap daily every afternoon for two hours. I then feel revived and can go on.

3) I feel that so far today in this conversation I have been clear and lucid in relating my illness. But I also feel that at times I become dull and sometimes lose my train of thought temporarily. I attribute this to the medication I take as prescribed. I feel very well oriented at this time.

I traveled today (as I did yesterday) from Philadelphia to New York by train to be examined by the doctors. I was able to negotiate the limited walking to the taxi, etc, and had no serious distress. I needed about 7 Nitroglycerin tablets during the past 24 hours.

The patient states that when he is on vacation with his wife in Barbados he feels improved, namely, lack of anxiety, warm weather, less pain, rarely needing Nitroglycerin during the two week Holiday, ability to swim, and ability to walk up to 10 blocks. The patient states that the picture changes to chest pain as described above upon returning to Philadelphia.

PAST HISTORY: My first heart attack was in 1966 at age 48. I again had chest pain in July, 1966. I was again sick in 1967 with chest pain. I was then treated again in June, 1968 with chest pain diagnosed as coronary insufficiency. I had phlebitis of the left leg in 1972. My sixth attack of chest pain was in October, 1974. This was diagnosed as coronary insufficiency. In September, 1975 I had chest pain and had an angiogram which showed coronary artery disease.

I have been under the care of several physicians, including, Dr. Likoff, Dr. Segal, and Dr. Onesti. I visit Dr. Onesti on my routine check-up examinations, approximately every four weeks. My last visit was on February 9, 1976.

PHYSICAL EXAMINATION: The patient is an adult white male, well developed and well nourished, in no respiratory distress at rest or during the examination. The patient is alert, oriented and cooperative. He speaks freely. He claims to have chest pain which started prior to entering the office and took 3 or 4 Nitroglycerin tablets at intervals. He also took Isordil and a Valium tablet during the course of the history taking. All the chest pains were eventually relieved in the course of the examination. Weight 184 lbs., height 72½". The pupils are equal and regular. The ear, nose and throat examination is negative. The neck reveals no abnormal masses or pulsations. The thyroid is not palpable. Examination of the chest reveals the lungs to be clear, no rales. Examination of the heart reveals the point of maximum impulse at the mid clavicular line in the fifth intercostal space. The heart sounds are are of fair quality, no murmurs. There are no rubs. The rhythm is regular, 90 per minute. BP 110/70. The abdomen is soft. Liver and spleen are not palpable. The extremities reveal no clubbing, cyanosis or edema. The skin is clear. The skin is warm and slightly flushed in the neck and face. There is no sweating. There is no rash. The gross neurological examination is negative. The patient remains supine during the course of the examination and presents no evidence of respiratory distress.

Electrocardiogram: Normal sinus rhythm - AR=VR = 100. PR = 14, QRS = .09. L = DEA. T III inverted Q III Deep. Changes are consistent with previous (old) myocardial infarction. Clinical correlation is necessary.

CHEST X-RAY: Lungs clear. Heart is of normal size with some prominence of left ventricle. Cardiothoracic ratio 14:29.

LABORATORY DATA: WBC 6.4 thousand, RBC 5.4 million, Hgb. 15.3 gm%, HCT 48% Polys 65%, Bands 02%, Lymphs 30%, Monos 01%, Eos 02%, SMA-12 Calcium 10.6 (8.5-10.5mg%), Phosphorus 2.2 (2.5-4.5 mg%) Sugar 111 (65-115 mg%) BUN 18 (6-25 mg%) Chol 324 (50-300 mg%) Uric Acid 7.1 (2-8 mg%) Bilirubin Total 0.5 (0.1-1.2 mg%) Protein Total 7.0 (6-8.2 gm%) Albumin 4.9 (3.4-5.5 gm%) Alkaline Phosphatase 15 (10-50) SGOT 31 (10-50) LDH 44 (22-76). Urinalysis: Sp. Gr. 1.010, albumin negative, sugar negative.

DIAGNOSIS:
1) Cardiac
   a) arteriosclerosis and possible hypertension
   b) coronary atherosclerosis with old myocardial infarction
   c) sinus tachycardia - normal sinus rhythm - anginal syndrome
   d) Class 3C.
2) Diabetes Mellitus (History)
3) Thrombophlebitis, left leg (old)
4) Anxiety State.

FORMULATION: This 57-year-old male suffered his first cardiac episode, acute myocardial infarction, in 1966 at age 48. The illness was characterized by severe chest pain and the diagnosis was firmly established by progressive and characteristic enzyme changes as well as Ekg. findings consistent with inferior wall myocardial infarction. Subsequently, the patient developed recurrent episodes of chest pain which were less severe in nature than the episode of 1966 but which necessitated repeated hospitalizations to rule out further myocardial infarctions or other possible complications. The several hospital admissions in 1966, 1968, 1972, 1974, and 1975 confirm the presence of coronary artery disease, coronary atherosclerosis, and coronary insufficiency or angina pectoris but did not disclose any evidence of further episodes of myocardial infarction. The enzymes and Ekgs. taken at various times and serially were consistently normal or showed no change. During the last period of hospitalization (September, 1975), the angiographic studies of the coronary arteries showed severe coronary occlusive disease involving all three major coronary arteries with good collaterals which maintain the patient at his present cardiac status.

The patient presently complains of chest pain, recurrent, related to effort, cold weather and emotional stress. These pains are relieved by Nitroglycerin and other medication as prescribed. He is relatively free of chest pain when he can be on vacation or in a warm climate, or when in Philadelphia he can avoid exertion, cold weather and emotional stress.

The episodes of chest pain have been essentially unchanged in character and number since September, 1975 (about five months), eight to ten attacks daily for four or five days of the week, and in the past several days, pain at night has appeared.

DISCUSSION AND OPINION: The history, physical findings, laboratory data including Ekgs., coronary angiograms and clinical course establish the presence in this patient of heart disease due basically to coronary atherosclerosis. It is noteworthy that this patient suffered his first acute occlusive coronary episode about ten years ago at age 48 and his subsequent findings show no further episodes of myocardial infarction despite innumerable episodes of chest pain due to angina pectoris or coronary insufficiency. It is also notable that this patient has never manifested any evidence of congestive heart failure. Nor has he had any evidence of irregular heart action such as significant premature contractions or tachyarrhythmias.

The clinical course of heart disease is not uncommonly along one of two lines, namely, a course characterized by congestive heart disease (pump failure) with relatively little pain or a course dominated by recurrent chest pain due to

coronary atherosclerosis with little or no evidence of congestive heart disease.

The present case of heart disease is due to coronary occlusive atherosclerosis.

A fuller understanding of atherosclerosis requires a correlation of its clinical manifestations with its inherent nature and development.

Atherosclerosis is best considered to be the biological response of the lining or intima of blood vessels to the fluid forces generated by the flowing blood itself. As blood flows through the blood vessels, including the coronary arteries, it exerts varying mechanical stresses on the walls of the arteries at very specific areas or zones of predilection. These sites of predilection are characterized by tapering, branching, bifurcation, curvature, and external attachment. At such locations, the flowing blood exerts a suction or pulling effect - a tensile force - which stimulate the intima to thicken or proliferate. The intimal thickening becomes the atherosclerotic plaque. The wall thickens and encroaches on the channel or lumen. This reduces the volume of blood flow slowly and progressively in the blood vessel involved. Eventually, at a critical stage of occlusive narrowing of the channel, the heart muscle suffers a permanent lack of sufficient blood supply and becomes necrotic - a myocardial infarction results.

Further details of the Hemodynamic Basis of Atherosclerosis are available in published research reports from my laboratory to which reference is respectfully made.

In the present case, it is clear that this patient suffered a cardiac episode ten years ago due to occlusive changes sufficient to cause an acute myocardial infarction. This was not related to any factor such as rest, exertion or emotional stress - it was due to the progressive course of antecedent coronary atherosclerosis.

The inherent pathological course of atherosclerosis is variable and unpredictable. Atherosclerosis may remain relatively stationary and clinically stable for long periods. It is also subject to gradual and progressive change. It is also subject to abrupt and dramatic episodes including sudden death.

The present case has been characterized by repeated episodes of chest pain clinically. During the past ten years many episodes were severe enough to suspect further myocardial infarction but none has occurred despite numerous stressful episodes in the patient's daily life over this period.

The occurrence of a further myocardial infarction in this patient will result from his underlying progressive coronary atherosclerosis and this cannot be predicted with respect to time. Coronary atherosclerosis is not produced by anxiety, emotional stress or environmental factors such as cold weather, etc. Atherosclerosis is a sequel to blood flow itself as the primary cause in accordance with the effects of the laws of fluid mechanics when applied to the human circulation including the coronary arteries.

OPINION: This patient has severe and advanced coronary artery disease, coronary atherosclerosis. He is subject to chest pain due to angina pectoris or coronary insufficiency following exertion, exposure to cold weather or emotional stress. These are physiological and reversible phenomina and subside when the disproportion between blood supply and demand is restored by taking Nitroglycerin or resting. These episodes do not cause or influence the natural course of atherosclerosis. Atherosclerosis is the biological response of the lining of blood vessels to the forces generated by the flowing blood (diminished lateral pressure) at sites of predilection in the circulation in accordance with the effects of the laws of fluid mechanics.

Although this patient may be expected to experience chest pain due to angina pectoris or coronary insufficiency if exposed to an emotionally stressful environment, this can be expected to be controlled as in the past ten years, by appropriate medication including Nitroglycerin.

There is no intent to predict with unfailing accuracy the course of coronary atherosclerosis in any patient because of the inherently progressive and unpredictable nature of atherosclerosis. Nevertheless, the clinical course of this patient is well documented for ten years and innumerable episodes of angina have occurred with relief by rest and/or Nitroglycerin.

In my opinion, although this patient may experience chest pain in a court proceeding, it is very unlikely and only remotely possible that a myocardial infarction will occur as a result of his antecedent atherosclerosis at precisely the time of his participating in a court proceeding.

Further untoward clinical reactions or manifestations of this patient's heart disease, such as tachyarrhythmias or congestive heart failure are, in my opinion, most unlikely now, since they have not appeared during the past ten years.

The court may find intthe above presentation of this patient's cardiac status a basis upon which to base its own decision.

Very truly yours,

Meyer Texon

Meyer Texon, M. D.

MT/mc

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA

-V-

75 Cr. 753 (CRM)

Affidavit

EDWARD PASTOR and MARTIN WEINER

Defendants.

STATE OF PENNSYLVANIA)
COUNTY OF PHILADELPHIA) SS:

GADDO ONESTI, being duly sworn, deposes and says:

1. I am a physician licensed to practice medicine in The State of Pennsylvania. As such I have been treating Edward Pastor since 1966, when he first had a myocardial infarction.

2. Mr. Edward Pastor has been complaining of nocturnal crescendo angina for the past two weeks.

3. On Monday, February 16, 1976 in the early morning hour, Mr. Pastor developed severe chest pain over the precordial area, left shoulder, and left arm associated with shortness of breath and sweat. The pain lasted approximately 2½ to 3 hours and was followed by a persistent dull ache over the left side of the chest.

4) Mr. Pastor was examined at noon (February 16, 1976) in the Hahnemann Feinstein Polyclinic. His blood pressure was 160/100. His heart rate was 98 and irregular. Basilar rales were detected at both pulmonary bases. He was transported by stretcher to the Hahnemann Hospital Coronary Care Unit with the admission diagnosis of Acute Myocardial Infarction.

5) In the Hahnemann Coronary Care Unit he was diagnosed to be in congestive heart failure and acute myocardial infarction.

6) Final diagnosis pending daily serial blood enzyme studies: Precise determination of necrosis of the myocardium depends in part on multiple sequential examination of cardiac enzymes for several days.

7) The possibility of acute lung embolisms is also considered in view of the clinical picture and his past history of thrombophlebitis of the lower extremities.

8) At this time, the duration of hospitalization in the Coronary Care Unit and in the Hahnemann Hospital cannot be determined. It is estimated that it will not be less than two weeks. His convalescence period, confinement to the house, is estimated to be approximately two-three months.

9) We advised Mr. Pastor not to exert himself with any exercise. This would seriously aggravate his cardiac status.

Gaddo Onesti, M.D.

Gaddo Onesti, M.D.
Professor of Medicine
Division of Nephrology & Hypertension

Sworn to before me
this 18th day of February,
1976

Dorothy Moors

DOROTHY MOORS
Notary Public, Philadelphia, Philadelphia Co.
My Commission Expires August 8, 1977

KUH, SHAPIRO, GOLDMAN, COOPERMAN & LEVITT, P.C.
800 THIRD AVENUE
NEW YORK, N.Y. 10022
(212) 888-7000
CABLE: JUREQUAL
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ROBERT N. COOPERMAN
ROBERT E. GOLDMAN
RICHARD H. KUH
JACK B. LEVITT
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MILTON S. SHAPIRO
—
ANDREW R. COOPER
BARRY J. PINKOWITZ
HARVEY SCHWARTZ
EDWARD S. WACTLAR

PAUL L. WEIDEN
N.Y. AND EUROPEAN OFFICE
DONALD C. FARBER
JERRY BREGSTEIN
COUNSEL
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RECEIVED
MAR 4 1976
JUDGE MOTLEY'S CHAMBERS

March 4, 1976

File
cmm

Honorable Constance Baker Motley
Judge of the U.S. District Court
Federal Courthouse
Foley Square
New York, New York 10007

Re: United States v. Pastor and Weiner

Dear Judge Motley:

We write to your Honor in connection with the understanding reached with your very able Mr. Farmer by telephone yesterday pursuant to which the medical hearing, at which Dr. Texon was to testify, that had been scheduled for today, was cancelled.

Acting for Edward Pastor, we stipulate that the recuperative period required by the congestive heart failure for which Mr. Pastor was hospitalized on February 16, 1976 should not predictably extend past May 17, 1976. We further agree, as Mr. Pastor's lawyers, that no contrary claim will be made by us.

We so stipulate premised upon the affidavits of Dr. Gaddo Onesti, sworn to February 18, 1976 and Dr. Bernard L. Segal, of like date, both of which affidavits were marked as exhibit E in the proceedings before your Honor that took place February 18, 1976. At paragraph 8 of the Onesti affidavit, concurred in by Dr. Segal, after estimating that Mr. Pastor's hospitalization would be not less than two weeks (we are informed that Mr. Pastor was released from

the hospital on March 1, 1976), Dr. Onesti states: "His convalescent period, confinement to the house, is estimated to be approximately two-three months". As May 17, 1976 allows such a convalescent period, and as Dr. Kuhn informally -- premised upon his examination of Dr. Texon's report dated February 23, 1976, and the Hahnemann Hospital records from February 16, 1976 through February 22, 1976 -- indicated to us that May 17th would allow a reasonable convalescent period, we are stipulating as above.

It should be clear, as we indicated by telephone that this stipulation on the part of lawyers cannot, of course, bear in any fashion upon Mr. Pastor's very grave heart condition, and its ultimate impact upon Mr. Pastor's capacity to stand trial. That condition not only now includes the triple coronary heartocclusion, and the debilitating impact of the earlier myocardial infarction, but now is compounded by the added problems suggested by the recent congestive heart failure. Not only as officers of the court, but as Mr. Pastor's attorneys, we hope that -- in some fashion -- his overall condition will so improve as to enable him to stand trial, and to get the criminal charges behind him. But in light of his cardiac history, and of all medical opinion that we have seen concerning him -- even Dr. Texon's, at this point -- we cannot be sanguine about his ability to stand trial. Therefore, nothing that we stipulate herein is intended to waive the right to question -- in the interest of his life and health -- his ability to stand trial in Mid-May, should such inquiry then seem necessary.

Respectfully,

Richard H. Kuh

Richard H. Kuh

RHK:rac

cc: John Timbers, Esq.
Assistant United States Attorney
Donald W. Sparks, Esq.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA

-V-

75 Cr. 753 (CRM)

Affidavit

EDWARD PASTOR and MARTIN WEINER

Defendants.

STATE OF PENNSYLVANIA) SS:
COUNTY OF PHILADELPHIA)

BERNARD L. SEGAL, being duly sworn, deposes and says:

1. I am a physician licensed to practice medicine in The State of Pennsylvania. As such I have known Edward Pastor as a patient since September, 1974. My partner, Dr. William Likoff, has known Mr. Pastor, and treated his heart condition, since 1966.

2. Mr. Pastor is now hospitalized under my direct care in the Coronary Care Unit of Hahnemann Hospital, in Philadelphia, with the admission diagnosis of acute myocardial infarction and congestive heart failure.

3. I have read the affidavit of Dr. Gaddo Onesti, dated February 18, 1976, and fully concur with the clinical description and conclusions made by him.

Bernard L. Segal

Bernard L. Segal, M.D.
William Likoff Cardiovascular Institute
Hahnemann Medical College and Hospital

Sworn to before me
this 18th day of February,
1976

Katherine Jane Conn

KATHERINE JANE COHN
Notary Public, Philadelphia, Philadelphia Co.
My Commission Expires Sept. 25, 1978

KS

310a

LESLIE A. KUHN, M.D., P.C.
THE MOUNT SINAI HOSPITAL
1176 FIFTH AVENUE
NEW YORK, N. Y. 10029

TELEPHONE (212) TRAFALGAR 6-9009

May 18, 1976

Leslie A. Kuhn, M.D., being duly sworn, deposes and says:

I examined Mr. Edward Pastor at the emergency room of Mt. Sinai Hospital at approximately 10 A.M., May 18, 1976. Mr. Pastor has a previous history of advanced, triple vessel coronary artery disease, previous myocardial infarction, hypertension and severe angina pectoris. On the morning of May 18, 1976 he experienced two hours of severe, crushing anterior chest pain with radiation to the left arm. This was associated with diaphoresis and was unrelieved by 20 Nitroglycerin tablets. The pain continued during my examination.

On physical examination Mr. Pastor was in severe distress. The pulse was 72 and regular (patient taking Inderal). The blood pressure was 130/80 (right arm-supine). There was slight venous distention of the neck but no hepato-jugular reflux. The lungs were clear. The point of maximal impulse of the heart was not felt. There was regular sinus rhythm. There were no thrills or murmurs. The basal sounds were normal. The abdomen was normal. The femoral and pedal pulses were equal. There was no edema nor calf tenderness.

The electrocardiogram demonstrated previous inferior myocardial infarction. In addition, there were ST segment depressions in leads V4 through V6 suggesting acute myocardial ischemia. These changes were not present in his last previous record.

The findings are those of recurrent, severe acute myocardial ischemia with possible acute myocardial infarction or impending acute myocardial infarction in an individual with established, severe triple vessle coronary artery sclerosis, accordingly, Mr. Pastor was hospitalized for further observation and treatment in the coronary care unit of Mt. Sinai Hospital.

Sworn to before me this 18th day of may 1976.

/s/

/s/
Leslie A. Kuhn, M.D.

LAK/sgw

AMY ROSS
Notary Public, State of New York
No. 31-4622880
Qualified in New York County
Commission Expires March 30, 1978

311a

LESLIE A. KUHN, M.D., P.C.
THE MOUNT SINAI HOSPITAL
1176 FIFTH AVENUE
NEW YORK, N. Y. 10029

TELEPHONE (212) TRAFALGAR 6-9009

MAY 19 1976

EXHIBIT
U. S. Dist. Court
S. D. of N. Y.

May 18, 1976

Leslie A. Kuhn, M.D., being duly sworn, deposes and says:

I examined Mr. Edward Pastor at the emergency room of Mt. Sinai Hospital at approximately 10 A.M., May 18, 1976. Mr. Pastor has a previous history of advanced, triple vessel coronary artery disease, previous myocardial infarction, hypertension and severe angina pectoris. On the morning of May 18, 1976 he experienced two hours of severe, crushing anterior chest pain with radiation to the left arm. This was associated with diaphoresis and was unrelieved by 20 Nitroglycerin tablets. The pain continued during my examination.

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Sworn to before me this 18th
day of may 1976.

/s/

/s/
Leslie A. Kuhn, M.D.

LAK/sgw

AMY ROSS
Notary Public, State of New York
No. 31-4622880
Qualified in New York County
Commission Expires March 30, 1978

jwr18 Viana-cross

THE COURT: Yes, we are going to recess in a minute, Mr. Kuh.

MR. KUH: I do ask when we do recess that your Honor direct Mr. Timbers, Agent Viana and any other person present not to discuss any of the testimony we had on this issue in any fashion with any other DEA personnel.

MR. TIMBERS: There is no need to so instruct. The government always follows that practice, your Honor.

MR. KUH: I didn't hear Mr. Timbers' statement.

(Record read)

(Pause)

THE COURT: All right. What we are going to do in the morning -- the jury has been instructed to be here at 9 o'clock -- we are going to suspend the hearing and proceed with the selection of the jurors and send them home and then we will continue with this motion to suppress. So the jury will not be sitting later tomorrow morning.

The first thing tomorrow morning we are going to do is select the jury.

MR. KUH: Your Honor, I respectfully except

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and ask to be heard on that change in the order you set last Thursday.

THE COURT: Yes, you may be heard.

MR. KUH: I was in great pain Thursday -- we were only here a little over two hours as I recollect. Today we have been here four hours. This last hour I have had considerable trouble.

In light of Thursday obviously the record -- not here in this courtroom, but on this case will show that by the following morning, Friday, we filed a motion in the Court of Appeals and that compelled me to work, although some of my work was done lying down Thursday and continued on Friday.

In light of the agony, and I mean agony, that I have been going through, I consulted on Friday with my partner Robert Goldman to see if on the basis of what took place today and possibly tomorrow, if the hearings continued, if he thought he would be able to take over, because I cannot sit here four hours a day; it's impossible.

I have also consulted with my client on that and my client indicated he wanted my services. If he has no choice -- and he has none because I can't continue this day after day -- reluctantly he will take

jwr20

such counsel as we advise.

Mr. Goldman did clal me over the weekend. I ave him some of the files to take homeso that he could get the drift of it and he indicates he doesn't see how he can be prepared, but what must be, must be.

I therefore ask your Honor that we continue these hearings, and I will see it through, and when they are completed, hopefully tomorrow, Wednesday, whatever, then I will ask you Honor that we be given a day or two recess before jury selection starts so that Mr. Goldman can prepare and try this case. Even with such recess I suggest Mr. Paster will neither have counsel of his own choosing nor will have counsel adequately prepared.

I just can't -- and I never asked any Court anywhere -- and I have been a member of the bar almost 30 years now -- I never asked anything like this before, but I cannot proceed. And I am not prepared in any fashion to start the trial tomorrow. And I would ask, if the jurors can be notified -- maybe it can be indicated it's a false start -- that we get the hearings out of the way and then your Honor give us, I would like to ask until next week, to give Mr. Goldman at least an ounce of time to start preparation for trial.

But if your Honor is going to persist in a

jwr21

four-hour day under both doctors' orders and my own reaction to my own pain, I just cannot proceed.

THE COURT: All right. If there is nothing further, we are going to recess until 9 o'clock tomorrow morning. The jury was here all morning. And I don't intend to have them sit here again tomorrow morning. We will select the jury and let them go home and hopefully we will finish this hearing tomorrow, but at the moment it looks like it's going to be a long drawn out hearing.

So we will select the jury and let them, as I said, go home and we will finish this hearing and take up other preliminary matters.

MR. KUH: I wonder then this, your Honor, in the interests of my own health -- I guess in a court of justice one has no right to talk about the welfare of a person involved, but I do ask if your Honor is going to have the jury selection tomorrow, since this is a serious felony case, that then your Honor recess this until Wednesday and at least I can stay lying down tomorrow. I am in pain and I don't think the Court should trifle with the health of counsel any more than with the health of a client. And I do object to my then -- then Mr. Goldman will handle the jury business tomorrow

jwr22

unprepared, but will handle it, and then I would be directed, I guess, if that is completed tomorrow to come back on Wednesday.

I would ask if the Court can set that schedule. And I urge that as not waiving my exception. I think the wise schedule would be to follow what your Honor said the schedule was on Thursday, that there be three hearings conducted and when they were completed they could be followed by the beginning of the trial. And I urge that your Honor changes your mind. One never knows what the law is in this case and the procedure from moment to moment.

THE COURT: Well, these hearings are taking much longer than anticipated. We have only now just gotten underway and we will take at least another couple of hours from the number of witnesses indicated just by the government. Two more?

MR. TIMBERS: Yes, your Honor. The government has Al Cavuto and Harry Weinkauff prepared to testify.

THE COURT: And from your cross-examination, as you commenced it of Mr. Vigna, that is going to be a long time if we are going into the matters which you indicated.

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So, as I said, rather than have the jury sit here tomorrow morning again waiting for this trial to commence, we will select the jury and let them go and continue with this suppression hearing.

It has to do with two statements, is that it?

MR. TIMBERS: That is correct, your Honor.

THE COURT: On the part of Mr. Pastor.

MR. KUH: Might I suggest, your Honor, there is a Wade hearing also to follow and it's directed that this witness took more than an hour and I assume my cross will take far more than that. And hence we are talking about at least another day, and probably realistically if we consider the Wade hearing as well, two days.

To have the jury selected and then sitting around, your Honor, is not solicitous of their welfare. I would urge that word be sent to the jurors today that they are not needed tomorrow and we get these hearings over with and that at least that will give Mr. Goldman some time to prepare for the trial. It will also permit the jurors from having been held in abeyance when selected for one day or two days, and we don't really know how many days.

THE COURT: All right. Recess to 9 o'clock

jwr24

tomorrow morning, at which time we will select the jury and then continue with these hearings.

MR. KUH: May I be excused and during the mid-morning break your office can notify my office when we will be reached and Mr. Goldman handle the jury selection?

THE COURT: All right.

MR. TIMBERS: I am very reluctant to burden the Court. The Court has directed Mr. Pastor be examined every two days and I tried to make arrangements with Mr. Kuh for the procedure. Mr. Kuh refuses to talk to me about it off the record so we'll need the Court's assistance for Mr. Pastor to be examined.

I am very sorry to burden the Court with this matter.

THE COURT: What is the problem, Mr. Kuh?

MR. KUH: The problem essentially, your Honor, as I indicated to your Honor, is that Dr. Texon serves as an agitant rather than someone to improve Mr. Pastor's health. If your Honor will not entertain the alternative of presenting a list of accredited cardiologists and if your Honor insists this is the only step your Honor will take to protect Mr. Pastor's health then obviously we will submit, but I would ask

jwr25

then that the arrangements be made that Dr. Texon see Mr. Pastor here someplace at the close ofthe session so that Mr. Pastor other than being in court each day can go to his hotel room and sleep and rest and take it easy and not go running all over New York to add to his irritations.

THE COURT: Where is Dr. Texon going to examine, in his office?

MR. TIMBERS: Well, that is what I wanted to discuss with Mr. Kuh. I would be glad to approach Dr. Texon and determine whether he can examine Mr. Pastor in Mr. Pastor's hotel room every second day at a pre-arranged time in the afternoon.

THE COURT: All right. We will let it go at that.

(Adjourned to May 18, 1976, at 9:00 a.m.)

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UNITED STATES OF AMERICA

vs.

76 Cr. 253

EDWARD PASTOR and MARTIN WEINER.

New York, May 18, 1976;
9.00 o'clock a.m.

- -

(In the robing room.)

THE COURT: Is the Government ready to proceed?

MR. TIMBERS: The Government is ready to proceed, your Honor.

THE COURT: Is the defendant ready to proceed?

MR. COOPER: The defendant Pastor is not ready at this time.

THE COURT: Is the defendant Weiner ready to proceed?

MR. SPARKS: Yes, your Honor.

MR. COOPER: If I may explain:

I received a call in my home at about 8.15 this morning from Mr. Kuh who is counsel of record in this case for Mr. Pastor. Mr. Kuh informed me that he had been informed by Mr. Pastor's wife that Mr. Pastor had another

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heart problem I believe early this morning; that she had to administer oxygen; that she could not even get Mr. Pastor clothed this morning he was in such bad shape.

Mr. Kuh further informed me that upon hearing that he called Dr. Texon, not having been able to reach Mr. Timbers, who I believe was on his way in from Connecticut. He asked Dr. Texon if he could go to the hotel where Mr. and Mrs. Pastor were staying and examine Mr. Pastor and, if necessary, admit him to the hospital. Dr. Texon said he could not do that; that he is not authorized by the Court to do that; that he doesn't have a Court order and therefore he would not do that.

I was informed that Mr. Kuh within the last 15 minutes called Dr. Texon again. Dr. Texon still said he was not able to go to Mr. Pastor. I believe Dr. Texon said that he would be in his office and if Mr. Pastor could get to his office he would be able to examine him there, but my information is that Mr. Pastor was not in condition even to be dressed, no less to go out of the room.

In talking with Mr. Kuh in the last five minutes he told me that he also called Dr. Kuhn who was to get back to Mr. Kuh within the next ten minutes and inform him as to what his findings are. I don't know

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whether Dr. Kuhn will be able to see Mr. Pastor or not.

THE COURT: By when?

MR. COOPER: He is going to call back in the next ten minutes. I don't think he will have seen him by then.

What I would request is this: I know Dr. Texon has been examining Mr. Pastor as the Court's direction. I would believe if Dr. Texon were ordered to examine him again that he would. I believe the reason Dr. Texon said he wouldn't at this time is because he wasn't authorized.

I would ask that the Court through a phone call at least now order Dr. Texon to examine Mr. Pastor at Mr. Pastor's hotel.

THE COURT: I don't have any doctor's certificate here, Mr. Cooper, saying that Mr. Pastor is unable to attend court this morning, so his bail is revoked and the United States Marshals are ordered now to go and get him. We are going to proceed in his absence.

MR. COOPER: May I ask --

THE COURT: If you say another word you are going to need a lawyer.

Now, let's go.

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(Pause.)

THE COURT: Mr. Timbers, do you have something to say?

MR. TIMBERS: Yes, your Honor.

The Government is prepared to have Mr. Pastor examined and to have him placed in the Metropolitan Correctional Center if necessary. The Government would apply, however, to defer the selection of a jury to determine whether Mr. Pastor has purposefully absented himself from court today. The Government is concerned that if by chance Mr. Pastor should for once in fact be sick there might be Sixth Amendment problems in choosing a jury in his absence. The Government would apply at this time that a determination be made first as to whether he is in fact sick before proceeding.

MR. COOPER: May I say something?

THE COURT: The application is denied.

MR. COOPER: May I bring the Court up to date?

THE COURT: Yes.

MR. COOPER: I spoke to Mr. Kuh against. He said that he had spoken with Dr. Kuhn who in turn spoke with Dr. Texon. I believe it is the consensus of both Dr. Kuhn and Dr. Texon that Mr. Pastor should be examined. These arrangements were made before the Court made its

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previous order this morning.

Mr. Pastor, I believe, is at this time, if he has not already arrived, is on his way to Mount Sinai Hospital's emergency room either by ambulance or taxi, whichever was able to be arranged first. I believe Dr. Texon is aware of this fact now.

I would ask the Court that the Court's reason for revoking bail and ordering the marshals to get him because there was no doctor's note, to at least give us an hour to get the note. This set of circumstances was just brought to my attention and I believe just happened. It was not possible to get a doctor's note down here by that time.

THE COURT: The application is denied.

MR. COOPER: If your Honor please, before we proceed I would make the same objections to having to go forward without Mr. Pastor at this time. I believe he has a right to be here until it is determined --

THE COURT: He has a right to be here, but he also has a responsibility to present a doctor's certificate saying that he is unable to be here. This is a deliberate attempt to frustrate this Court in bringing this case to trial and I'm not going to hear it again. That is my conclusion, that this was done deliberately to

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frustrate this Court from selecting a jury this morning at 9 o'clock as you full well knew as did Mr. Kuh and Mr. Pastor.

MR. COOPER: You are not saying it is a deliberate attempt.

THE COURT: I just ruled that it is my view that it is because I changed the schedule and Mr. Kuh didn't like it, so we are going ahead. Let's go into the courtroom.

MR. COOPER: I have an application to make as to the jury selection procedure and the number of challenges.

THE COURT: You will have the same number of challenges. No additional are needed. There are only two defendants.

MR. COOPER: May I be heard on that? Mr. Timbers supplied me this morning with requests for voir dire about five or ten minutes ago.

THE COURT: I looked at them. They are the usual, normal ones.

MR. COOPER: I have only had an opportunity to look at the first page, but I noted on the first page --

THE COURT: You can look at it while we go ahead. I will stop at the end and ask you if you have

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any more.

MR. COOPER: There is an objection I have on the first page where Mr. Timbers refers to this as a narcotics offense.

THE COURT: I will delete that.

MR. SPARKS: I noticed -- Mr. Timbers just gave me a copy this morning a few minutes ago, and I likewise consistently noticed throughout the first question and in the sixth question he uses the terminology narcotics offense.

THE COURT: I will delete that. I noticed that.

MR. COOPER: Is the Court going to bring to the panel's attention the fact of Mr. Pastor's absence? Is it going to make any comment upon that?

THE COURT: I will just say that he is not here at the moment and we are going ahead. That is my view of it and if the higher court overrules me -- that is my view, that it is a deliberate attempt to frustrate this Court. I may be overruled by a higher court, but that is my ruling.

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(Jury and two alternates were duly impaneled)

MR. TIMBERS: Your Honor, may we approach the bench?

(At the side bar)

MR. TIMBERS: Your Honor, my office has informed me that Mr. Kuh has called our office because he could not get in touch with his colleagues in the courtroom to say that Mr. Pastor has entered Mt. Sinai Hospital and that Mr. Kuh expects to have an affidavit from Mr. Pastor's doctor, Dr. Kuhn, for the Court.

THE COURT: What about it?

MR. TIMBERS: I want to convey that message to defense counsel and to the Court. This was the message which was called into our office because Mr. Kuh could not get in touch with his colleagues and I wanted to notify the Court and the defendants of this.

THE COURT: We haven't taken any testimony yet in this case. I don't understand the reason for raising that.

MR. TIMBERS: I have no reason, your Honor. I simply have received the message and I thought I should convey the information to both the defendants and to the Court.

THE COURT: All right.

(In open court)

THE COURT: Mr. Clerk, do you want to swear the jurors and the alternate jurors.

(Jury and two alternate jurors were duly sworn)

THE COURT: All right. Ladies and gentlemen, first of all I want to tell you that we have utilized this courtroom solely for the purpose of selecting a jury. It's a larger courtroom than the one in which we will actually try the case.

The courtroom in which we will actually try this case is courtroom 2703 and after I get through with the preliminary instructions to you the clerk going to take you up there and show you to the jury room adjoining that courtroom and that is where you are to report tomorrow morning at 9 o'clock.

Now, as I indicated earlier, the trial of this case will be different from the trial in most cases in that we will have a four-hour session each day commencing at 9 o'clock and we will recess for the day at 1 o'clock.

During that four-hour period, of course, we will take an appropriate recess, but the trial will start

each day at 9 o'clock and we will recess at 1 o'clock.

Now, in addition to those preliminary instructions, I want to give you some additional preliminary instructions.

The first is that during the course of the trial you must pay careful attention to the testimony which you will hear from various witnesses and you must pay careful attention to the other evidence in the case which will come in in the form of exhibits.

The reason that you must pay careful attention must be obvious to you, and that is as the jurors in the case it is going to be your exclusive function to decide the facts inthe case.

Obviously if you have not been paying attention, or if you have been falling asleep or lettering your mind wander, you are not going to be able to perform that function very well.

So the first instruction is to pay careful attention when you are in the courtroom while evidence is being received, that is testimony and exhibits and perhaps some stipulations as to certain facts which the lawyers might enter into.

As I told you earlier, this is a criminal case and in a criminal case the defendant doesn't have

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to say anything. The defendant doesn't have to call any witnesses, doesn't have to take the witness stand, doesn't have to present any evidence. That is because in a criminal case the government has the burden of proof, and that is to prove the defendant guilty of a particular charge beyond a reasonable doubt.

As I pointed out earlier, also, in a criminal case a defendant is presumed innocent and the fact that he doesn't offer any evidence or take the stand or anything like that should not be held against him, that is you can't infer anything from his failure to offer evidence or to take the witness stand. And that is because, as I said, under our system a defendant is presumed innocent and he remains innocent until after the jury has deliberated in the jury room and the jury finds that the government has sustained its burden of proof, which is to prove the defendant guilty beyond a reasonable doubt, it is only then that the presumption of innocence is removed.

I want to remind you again that an indictment is not proof or evidence. It is merely an accusation or a series of accusations. It is a method which we employ in our system whereby a person is charged with the crime by a grand jury and then the defendant is brought into court and it is only then that his guilt or innocence is

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determined by a petit jury such as you are. So that the indictment has no evidentiary value.

It is going to be my duty to instruct you as to the law applicable to this case and that I will do at the end of the entire case, after all the evidence is in and the lawyers have had an opportunity to sum up.

During the course of the trial, it is going to be my duty to rule on motions and objections made by the lawyers on both sides.

These things should not concern you -- my rulings on these matters -- because they have to do with questions of law and they will concern the administration or running of the trial, so to speak, housekeeping matters.

As I said, your duty is to focus on the evidence and the evidence in a case consists of three things:

First, it consists of testimony which you will hear from witnesses who will take the witness stand right in front of you so you can hear them and see them. As I said, it will be a much smaller courtroom where the acoustics will be much better than they are here. So you will be able to observe the witnesses as they testify, observe their manner and demeanor while

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on the witness stand, because you are going to have to assess the credibility of each witness at the end of the case during the course of your deliberations.

The evidence in the case also consists of certain exhibits which are actually received in evidence. There will be some exhibits offered in evidence which will be received and others which are not. So only those exhibits actually received in evidence constitute part of the evidence in the case.

And, finally, the evidence in a case consists of any stipulations, that is agreements as to certain facts which the lawyers might enter into. For example, they might agree that if a witness were called to testify to the following effect, without the necessity of calling the witness. That we call a stipulation.

So those three things constitute the evidence in the case, that is the testimony, the exhibits and any stipulations or agreements as to certain facts.

All of that is to emphasize that statements made by lawyers or by the Court during the course of a trial is not evidence and when the trial commences tomorrow morning we aregoing to have an opening statement by the government counsel. And, as I told you, a defendant need not offer any evidence, need not say anything.

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On the other hand, the defendant may, if he wishes to do so, make an opening statement, in which case you will have opening statements by defense counsel.

During the course of the opening statement it will be the government's responsibility to outline for you what it expects to prove because as I said statements made by lawyers is not evidence. What the government's lawyer will be doing will be telling you what he expects to prove by various witnesses and by the introduction of various documents into evidence.

And then, as I said, after that the trial will begin with the actual receipt of evidence.

As the evidence comes in, you will want to keep an open mind until you have heard the whole case from both sides. For that reason you must refrain from discussing the case among yourselves or with your family or your friends when you go home at night. You must not discuss the case at any time among yourselves until after the Court has instructed you as to the law applicable to the case because that is the only time you will have the whole case before you because at that point all the evidence will be in, all the lawyers will have had an opportunity to sum up and the

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Cou t will have an opportunity to instruct vou as to the law.

Once that is accomplished you have the whole case before you and that isthe only time vou are permitted to discuss the case among yourselves, when you have finally retired to the jury room to deliberate.

As I said again, the reason for that is you have to keep an open mind until you have heard the whole case and you can't keep an open mind if you discussed it long before you heard all the evidence and the Court's instructions as to the law.

Because you must keep an open mind and decide this case solely on the basis of the evidence presented in court, youa re not to go home at night and discuss the case with your family or your friends because if you do that the first thing you know somebody will start telling you about what they read in the newspaper or saw on the television or heard on the radio, and although you do not intend it those discussions are apt to influence your judgment here. And, as I told you repeatedly now, your judgment in this case must be based solely on the evidence presented in court, the testimony, exhibits and stipulations and not on what somebody heard on the radio or saw on television or read in the

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newspaper. So please do not discuss the case when you go home at night.

You are not to discuss the case with any party in the case, you are not to talk to any lawyer in the case, or any of the defendants on trial, or any of the witnesses if you should happen to see them in the elevator or out in the hallway or anything of that kind. You are not to permit anyone to approach you about the case. If that should happen please don't tell your fellow jurors about it, but let me know immediately and I will take care of it.

So do not talk to anyone at any time in the hall or in the elevator, do not permit anyone to approach you for the purpose of discussing this case.

If you have any questions relating to your comfort or convenience, you can discuss them with Mr. Weinberg, our clerk here, and he'll try to resolve it. If not, he'll take it up with me. That relates to your comfort or convenience. But other than that, you are not to discuss the merits of the case with anybody at any time, for any purpose until you have finally retired to the jury room and to deliberate.

There is a cafeteria on the 28th floor in the courthouse. We will be on the 27th. You are not to use

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that cafeteria. It's not a public cafeteria. That cafeteria is for employees in the building and that includes United States Attorneys and other people involved in cases. So if you go up there you are apt to run into people discussing this or some other case among themselves. So please do not use the cafeteria on the 28th floor. That is not a cafeterial for jurors.

Should anyone telephone you or talk to you about this case, please do not tell that to your fellow jurors, but let me know immediately. If there should be any publicity about this case, you aer not to read about that in the newspaper. If you should do so inadvertently, when you come in in the morning do not discuss that with your fellow jurors, but let me know immediately.

Again I don't know whether there will be any publicity, but if there is you are not to read any newspaper stories about the case.

I am sure that you know that when you serve on a jury youare playing a vital role in the administration of justice. I am sure that you know also that trial by jury is a basic and cherished institution in our system. I am sure that each of you who is now serving on this jury would want to give the

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parties who are now on trial the same fair trial which you would expect if you were a litigant in a lawsuit. For that reason I am sure you will want to pay careful attention, as I said, follow the Court's instructions, which I have just given you, so that you can give these parties a fair and impartial trial.

Now, as I said, we are going to recess at this time until 9 o'clock tomorrow morning. And the clerk will now show you to the jury room and adjoining room 2703 and you will report there in the morning at 9 o'clock.

No juror is permitted to be late coming to the court. 9 a.m. Please arrive about ten minutes before so we can begin promptly at 9 o'clock. It's going to be a short day, until 1 o'clock.

Thank you very much.

JUROR NO. 6: You said it would involve several more days. Can we take notes?

THE COURT: You see this man sitting here right here. That is the court reporter. He takes down everything which is being said and then when you go to the jury room, if you want some of the testimony read back, he will read it back. You may take notes if you wish, but it would be difficult. You see he's using

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a machine.

JUROR NO. 6: If something came up I didn't want to forget, can I just write it down?

THE COURT: You can do that, yes, but it's better to try to pay attention and then have him read back the testimony which you desire. As I said, that would probably be better to do. But you may take notes, if you wish.

All right. You may now follow the clerk to the courtroom.

(The jury left the courtroom)

(In open court; jury not present)

THE COURT: All right. We are ready to now resume the hearing we had on yesterday.

MR.GOLDMAN: Your Honor, prior to that time, there are several matters I would like to bring to the attention of the Court. I will make several applications, your Honor.

The first one I think is, I have just been handed, which consitutes the total of my knowledge in the area, an affidavit by Dr. Leslie A. Kuhn, M. D., of Mount Sinai Hospital, a director of the Ames Coronary Unit, and he states that this morning Mr. Pastor was admitted to Mount Sinai Hospital, was examined by

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Dr. Kuhn, and Dr. Kuhn in fact did find clinical findings indicating that Mr. Pastor was in fact experiencing a heart seizure.

I have an affidavit here from Dr. Kuhn, your Honor, which I would like to hand up to the Court and have marked, and I have a copy for Mr. Timbers.

THE COURT: All right.

Mr. Timbers, is Dr. Texon scheduled to examine Mr. Pastor this morning?

MR. TIMBERS: Your Honor, the defendants and the government could not agree on a procedure for examination yesterday. I can tell the Court this, however: That Dr. Texon is available after 4:30 this afternoon to conduct an examination and I will ask him to go to Mount Sinai to conduct the examination .

THE COURT: What do you mean, the government and defense counsel cannot agree?

MR. TIMBERS: Your Honor, this is the same sort of petty dispute that we have had throughout this case. I told the defendants yesterday --

MR. GOLDMAN: I think that is unnecessary, your Honor.

MR. TIMBERS: -- that Dr. Texon could examine Mr. Pastor under certain circumstances and the

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defendant said that the only way that the examination could take place would be if the Court would order it and therefore we would have to come before the Court in order to set a time and place for the examination.

MR. COOPER: Your Honor, may I --

THE COURT: Read that, Mr. Reporter, what Mr. Timers just said.

(Record read)

MR. COOPER: Your Honor, if I may respond, it's completely -- or at least the implication is completely inaccurate. Mr. Timbers talked to me on the telephone I believe yesterday afternoon advising me if he could arrange for Dr. Texon to examine Mr. Pastor.

I said, "Fine, could it be done at his hotel?"

Mr. Timbers advised me he could not do that.

I said, "Could we arrange it to be done before court or at court or immediately after the session at 1 o'clock at court?"

Mr. Timbers said that was not possible either.

He said, "Could Mr. Pastor come to Dr. Texon's office either in the afternoon or possibly at 8 o'clock

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in the morning," that he would check with Dr. Texon -- that he would have to check with Dr. Texon.

I said, "To do either of those would unduly extend the day that the Court has already cut down to four hours for Mr. Pastor."

I said, "If we could possibly do it the other way we would prefer it that way."

I said Mr. Timbers should bring these facts to the attention of the Court and that if the Court found we could not have Mr. Pastor examined either at his hotel or in court before or after court then we would abide by whatever the Court rules. I didn't say we would not submit to any examination unless the Court so rules, but I said we would prefer to have it the other way because of Mr. Pastor's condition and because the Court, recognizing that condition, cut the court day down to four hours.

That is what I said to Mr. Timbers, your Honor.

MR. TIMBERS: Your Honor, the facts of Dr. Texon's schedule is that Dr. Texon is testifying in the Eastern District of New York starting at 2 o'clock every day for the remainder of the week, and therefore he could not examine Mr. Pastor starting at 1 after the

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court proceedings are over.

Dr. Texon's office day does not begin until 9:30. Therefore he could not come down to the courthouse to examine Mr. Pastor at 8 o'clock in the morning as the defendant suggested.

MR. COOPER: Your Honor, I didn't suggest that.

MR. TIMBERS: Dr. Texon --

THE COURT: Please don't interrupt Mr. Timbers. You know the reporter can't get both of you speaking at the same time.

MR. COOPER: I apologize.

MR. TIMBERS: The only time during the day that Dr. Texon is free is starting at 4:30 in the afternoon. He expects to be free a little bit earlier tomorrow afternoon at the Eastern District of New York, but that is the only practical time for the examination to take place.

THE COURT: All right. He'll examine at 4:30 each day from now on.

MR. COOPER: Today's examination will be in Mount Sinai Hospital; is that correct?

THE COURT: No, I sent the marshals for Mr. Pastor. He will be examined in the facility behind

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the courthouse.

MR. COOPER: Your Honor, when you previously stated this morning that Mr. Pastor's bail was revoked and sent for the marshals you stated as your reason for doing so we didn't present the Court with any statement or affidavit from the doctor. We have now done that.

Based upon that, would your Honor consider revoking your order to the marshals until at least Dr. Toxon --

THE COURT: No, because nobody obeyed that order and I had to during the course of the selection of the jury get the chief marshal to go and get him. That order was completely ignored. I gave that order at 9:10 this morning. If it was obeyed, he would be there now.

MR. COOPER: Your Honor, I believe it is the fault --

THE COURT: This was due to people disobeying my orders in this case. My responsibility is to see that the authority of this Court is not undermined by anybody, and it's consistently being done by the defendants in this case. That is my view.

I said it earlier this morning, that this was

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a deliberate attempt to frustrate the Court. And after Dr. Texon examines him I will consider whether he should be in the hospital or not. But right now he's not. He's going to be brought down to the Metropolitan Center right here where Dr. Texon can examine him there. He'll decide whether in fact he has any condition which prevents him from being here. According to this report, he has no such condition that prevents him from being here in court.

MR. GOLDMAN: Your Honor, may I direct the Court's attention to the third paragraph --

THE COURT: It doesn't say anything to that effect here.

MR. GOLDMAN: Your Honor, may I direct the Court's attention to the third paragraph, your Honor? And it says that "There were ST segment depressions in leads V4 through V6 suggesting acute myocardial ischemia."

That is a cutoff of blood flow to the heart which is reported this morning by Dr. Kuhn. That was the finding -- the flow of blood has been cut off.

MR. TIMBERS: He suggests the flow of blood might be cut off.

MR. GOLDMAN: No, it says in fact "There

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were ST segment depressions in V4 and V6" which suggest -- in other words, from the absolute clinical findings the doctor now suggests what that really means -- and he said --

THE COURT: I am not going to hear it. I just said there is nothing in this report that says he can't be here to stand trial.

MR. GOLDMAN: Your Honor --

THE COURT: So he is voluntarily absent as far as I am concerned. Right now we are going to continue with that hearing we started yesterday and try to get through with that.

MR. GOLDMAN: Your Honor, I have some further applications, your Honor, and matters to hand up to the Court.

Your Honor, I also have here, which I think must be part of the record, your Honor, a report of Mr. Pastor's doctor. Apparently there was some suggestion that such a document had not been previously provided. This is Dr. Bernard Seigel, your Honor, who is the head of cardiology at Hahnemann Medical College and Hospital.

This report, your Honor, indicates that since the last time the matter was discussed by the Court Mr. Pastor has suffered from congestive heart failure and this letter, your Honor, concludes, executed

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by Dr. Seigel, that there is no doubt that his appearance in court is an intensive emotional experience which may provoke the current angina, may precipitate acute myocardial infarction, acute pulmonary edema or sudden death.

Your Honor, I would like to have this marked.

THE COURT: No, I already ruled and received the evidence on that. I am not going to receive it.

MR. GOLDMAN: This is additional.

THE COURT: No, it isn't. It's another attempt to frustrate the Court and try to block this case going to trial. I have ruled on that issue. You have been up to the Court of Appeals. You are now bringing in something else.

MR. GOLDMAN: May we have it marked so we can identify the document later, your Honor?

THE COURT: Yes. I am not going to hear any such matter now.

MR. TIMBERS: What is the date of the letter?

MR. GOLDMAN: May 13, 1976.

And again I have a copy for Mr. Timbers.

THE COURT: All right, Mr. Vigna, you can resume

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the stand.

J O S E P H V I G N A resumed.

MR. GOLDMAN: Your Honor, I have some applications to make.

THE COURT: All right. What are they?

MR. GOLDMAN: Your Honor, the first application is that -- or statement, is that by my appearance on behalf of Mr. Pastor in this case Mr. Pastor does not waive his right to counsel. I am here because Mr. Kuh is incapacitated and I have undertaken to try the case. I must state, however, that I did not know a single fact about this case until last Friday when it became apparent that Mr. Kuh could not continue.

I tried to garner as much as I could over the weekend. I did not meet Edward Pastor until yesterday afternoon and at the time that I met him he was unable to spend more than 15 or 20 minutes with me coherently, having been exhausted and under sedation from the morning court session.

Aside from the fact, your Honor, that my appearance is not a waiver of his right to counsel, I would like to suggest in the interests of the Court's stated desire to expedite this trial, several of the follwoing things:

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I would ask your Honor that in view of my circumstances and in view of my unfamilarity with the case and in view of the disabilities under which I will be laboring, that the government furtnish at this time the 3500 material forthe following reasons:

If the defense, or I would receive this material only after a witness testified there is no way realistically I can confer with my client meaningfully to make any use of that material whatsoever.

Secondly, your Honor, my own knowledge of the case is so scanty and so skimpy my inability to confer with the client and my recent involvement in it that I make the suggestion,your Honor, so that we can expedite matters, so that we can begin working on matters now so they can be somewhat meaningful that I would ask your Honor to assist me possibly in asking the United States Attorney if he would so furnish me with that material at this time.

Absent that,your Honor, I would be required in the interests of having something other than a mere spectator's contest here, that after each witness testifies on direct, that I be given between half an hour to 45 minutes in order that I may make some attempt to digest what is happening with regard to the evidence

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in this case, and particularly with regard to the testimony of any witness.

That is the essential nature, your Honor, in terms of a housekeeping nature that I might expedite the trial.

I wonder what the government's view is?

MR. TIMBERS: Your Honor, Mr. Goldman is in fact new to the case, but I point out we have produced to the defendants some nine inches of material and he should have enough to keep him busy within the next day or so with that material.

I think it is totally improper for defendants to manipulate counsel in order to get the government to produce the 3500 material.

THE COURT: Yes. That is all that is being done here. The record is clear, the performance in this case is clear, that what we have is a manipulation by counsel in an attempt to frustrate the Court.

I am saying for the third time in this case there is an attempt by counsel -- you, Mr. Kuh, and Mr. Cooper --

MR. GOLDMAN: You are accusing me, your Honor, of any attempt to frustrate this Court?

THE COURT: Yes, I am accusing you, coming in

at the last minute in a case like this, telling the Court that you need time to study this matter. You are an associate of Mr. Kuh. You know all about it.

MR. GOLDMAN: I am a partner.

THE COURT: You appeared in the Schwartz case, didn't you?

MR. GOLDMAN: Wha has that got to do with this case, your Honor?

THE COURT: You knew Mr. Kuh was sick six weeks ago and you know I ordered the client, Mr. Pastor, to get another lawyer so we wouldn't be in this jam. So I insisted on following your advice and stuck with it.

If he wants to follow your advice and ignore the direction of the Court to get another lawyer, which he had a chance to do six weeks ago, then he's stuck with his decision. He doesn't have a right to disregard the directions of the Court which he has done here. He had a chance to get another lawyer six weeks ago. He didn't take it. If he wants to go along with whatever manipulations you are involved in, he will have to suffer the consequences.

MR. GOLDMAN: Your Honor, might I state that just on the facts, I myself was actually engaged on trial

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until last week and then last week I was on a hearing outside the United States. My first involvement in this case was on Friday.

There is nothing, your Honor, I have seen either prior to or during the brief time of my involvement that suggests a deliberate manipulation. I have seen a man suffering on the point of death and my partner in absolute agony in the last six weeks. That is the only thing.

THE COURT: We are going on with the case now.

MR. GOLDMAN: I understand that, but am I not entitled to when defamed by the Court on first impression, I am --

THE COURT: This is my conclusion based on the jury records here. The record will disclose that there has been a deliberate attempt here to prevent this case from going to trial. And you came in first of all late this morning with some excuse about some car accident.

MR. GOLDMAN: Yes, your Honor.

THE COURT: Coming to court late, first of all, without any prior notice to the Court. Mr. Kuh was here yesterday, as the record will show, vigorously defending Mr. Pastor every inch of the way. Without

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any notice he failed to show this morning.

Then we had Mr. Pastor at 8:15 deciding he is ill and can't come to Court. All of these things add up to what I have said.

MR. GOLDMAN: Your Honor --

THE COURT: No, we are not going to hear it any more and Mr. --

MR. COOPER: Your Honor --

THE COURT: Will you resume dthe stand.

MR. GOLDMAN: Your Honor, I have something further. Your Honor is identifying the application for 3500 material at this time.

THE COURT: I can't order the United States Attorney to turn it over. I told Mr. Kuh that last week. You took that up with the Court of Appeals which says you can't have it until after the witnesses testify.

MR. GOLDMAN: Your Honor, I would like to state also, having stated my background in this case and having stated conclusively, whether the Court accepts it or not, that I am not a party to or know of any attempt to manipulate or deliberately prolong this case.

I will say, however, your Honor upon coming to

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court this morning there is not once that the Court has addressed me since the first time I have appeared except for a short sentence when the Court did evidence in the presence of the jury displeasure at an utterance of defense counsel.

THE COURT: You say that once more that I uttered any displeasure in the presence of the jury. Be specific.

MR. GOLDMAN: Yes, I will be exactly specific, if I may check my notes, your Honor.

The first, your Honor, is, or the second, your Honor, was when I indicated that a juror had used the word "narcotics" in describing the pills here. At that time, your Honor, your Honor evidenced displeasure in that obviously I was making a frivolous application and then went on to say that in fact she hadn't heard it.

THE COURT: Where was that, in the presence of the jury?

MR. GOLDMAN: At the side bar: you were standing up.

THE COURT: And my back was to thejury as yours was?

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MR. GOLDMAN: Your Honor, I can't certify what the jurors saw or not.

THE COURT: Well, I am not going to listen to that because there was no displeasure on the part of the Court in the presence of the jury. I was careful to avoid that, and everything we took up was right here at the side bar so I am not going to listen to that.

MR. GOLDMAN: In addition to that, your Honor, on the basis of an innocuous act, your Honor in a voice which I believe could have carried to the jury and on personal impression intimidated or attempted to intimidate defense counsel by suggesting that for some act which I couldn't fathom I might be sent to jail by this court.

THE COURT: You know good and well why I chastised you about that act, waving to a juror to give the impression that you were the good guy in the case and the Court was the bad guy for not excusing that juror. That is the only impression the jurors could have gotten from your waving to them which you admitted you did. You waved your hand to that juror as he left the courtroom in the presence of the jury and you were less than ten feet from the jurors.

MR. GOLDMAN: And he was between me and the

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jury and it was not a wave, but the holding up of the hand which I do not characterize as a wave. But to be threatened to be sent to jail --

THE COURT: I am threatening you with jail. If you don't sit down and get on with this hearing, you will be in jail. You will find out whether judges run the court or lawyers. If you want to cross-examine those witnesses, it is your time now.

MR. GOLDMAN: Your Honor, may we send for Mr. Kuh who can only handle this part of the hearing?

THE COURT: No, you go on with it.

MR. GOLDMAN: Your Honor, yesterday you excused him and said he could come in on notice, your Honor. And it's on page 150 of yesterday's hearing.

THE COURT: How long would it take him to get here.

MR. GOLDMAN: The man can barely walk.

THE COURT: If he can barely walk, why is he coming here?

MR. GOLDMAN: Because we have no alternatives, your Honor.

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MR. TIMBERS: I think this is very unfair. The understanding I had yesterday and I think that everybody had yesterday was that Mr. Kuh's office would handle it. Mr. Goldman is pointing to a point in the record where Mr. Kuh said unilaterally:

"May I be excused and during the mid-morning break your Honor's office can notify my office and Mr. Goldman will handle the jury selection."

I think it is improper to put on the Court the burden of notifying Mr. Kuh.

MR. GOLDMAN: We will notify him. We haven't had a break.

THE COURT: We'll take one. You notify his office.

MR. GOLDMAN: His office or his home, maybe he is at home in bed.

THE COURT: You go on.

MR. GOLDMAN: I know nothing about this. Will your Honor give us a half hour?

THE COURT: I just said that. You said he was home in bed.

MR. GOLDMAN: I'm sorry, your Honor.

THE COURT: All right, we'll recess until tomorrow morning. We will dispense with the hearing on

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this until Mr. Kuh can get here, whenever he decides he wants to come to court. You go on with your other evidence, Mr. Timbers, that statement or whatever it is you are trying to introduce later on at trials

MR. TIMBERS: I should plan to proceed with four hours of evidence tomorrow, your Honor?

THE COURT: Yes, tomorrow morning we will begin with opening statements with the jury. We will take up these hearings later when Mr. Kuh feels like coming here to court.

MR. GOLDMAN: Don't these hearings have to precede the trial?

THE COURT: No, they do not.

MR. GOLDMAN: Is your Honor --

THE CLERK: Court is adjourned until May 19th at 9 a.m.

(Trial adjourned until May 19, 1976, at 9.00 o'clock a.m.)

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(In open court - courtroom 2703 - at the bench. Present: Mr. Timbers)

(3:10 p.m.)

MR. TIMBERS: After we broke from court this afternoon I called Dr. Texon up to find out what he knew about Mr. Pastor's situation. Dr. Texon hasn't had a chance to examine Mr. Pastor, but he has talked to Dr. Kuhn. I understand the situation through double hearsay. Dr. Kuhn does not find any objective proof of heart -- new heart problems. However, he feels that Mr. Pastor should remain in the hospital to be evaluated for a period of time.

Dr. Texon says that he sees no reason why he can't conduct this examination of that in Mount Sinai today and, therefore, the government would consent to Dr. Texon's examination taking place at Mount Sinai.

THE COURT: All right.

MR. TIMBERS: I will report back to the Court as soon as I hear from Dr. Texon.

THE COURT: Yes, get the report here as soon as you can.

MR. TIMBERS: Very good, thank you.

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UNITED STATES OF AMERICA,

vs. 76 Cr. 253

EDWARD PASTOR and MARTIN WEINER.

New York, May 19, 1976;
9.00 o'clock a.m.

(Trial resumed.)

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(In open court, jury not present.)

THE COURT: Good morning, gentlemen.

Dr. Texon.

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M E Y E R T E X O N , being first duly sworn, testified as follows:

THE COURT: Dr. Texon, I asked Mr. Timbers to call me last night and give me the essence of your report of your examination of Mr. Pastor. At this time I ask you to put on the record your report with respect to your examination yesterday afternoon of Mr. Pastor.

THE WITNESS: Thank you, your Honor.

I examined Mr. Pastor yesterday between 6 and 8 p.m., approximately, and found him in the Ames Unit at Mount Sinai Hospital. That is the coronary care unit.

I reviewed the hospital record. In fact, I reviewed it in the presence partly with Mr. Leslie Kuhn, his personal physician at the time.

I found in the record that he had been brought to the emergency room early in the morning and was complaining of severe chest pain, and in the words of Dr. Kuhn, which I quote, "He was admitted because of two hours of severe anterior chest and left arm pain unrelieved by 20 nitroglycerin tablets."

He was transferred to the Ames Unit and was treated as a case of myocardial ischemia, angina syndrome, and the possibility of a further acute myocardial infarction was suspected.

While in the Ames Unit he was investigated by the usual monitoring methods, continuous cardiogram, blood studies. And the blood studies which were available when I saw him revealed no evidence of myocardial infarction. The details are here, if you wish them.

The only significant objective finding was a change in the precordial leads in the electrocardiogram on admission, specifically some ST depression in leads 4, 5 and 6 of the precordial leads.

Further electrocardiograms during the day revealed reversion of that change to the previous record

which was essentially normal.

He was not febrile --

THE COURT: He was not what?

THE WITNESS: Febrile. There was no fever. There was no evidence of pulmonary congestion. He was not in congested failure.

The heart rhythm was normal, varied from 60 to 80 per minute.

His clinical status was that of a man complaining of chest pain periodically, sometimes relieved and sometimes not relieved by nitroglycerin.

At times the pain was so severe that he was given morphine injection which did relieve the pain, and he did receive at least three or possibly four injections from the time of admission to the time I left, which was close to 8 o'clock p.m.

My feeling was -- and I imparted this impression to Dr. Kuhn -- that this man's emotional status was such that he developed angina, perhaps more severe than on previous occasions, but nevertheless a reversible type of angina physiologically and that this was a case of again transient myocardial ischemia based on the underlying coronary atherosclerosis which we know he has to a severe degree.

He was relatively comfortable by the time I left. There was no respiratory distress at that time.

My feeling was that from an academic and medical standpoint, in view of the possibility that a further change may occur, that he should remain where he was for at least another 24 hours and that if improvement continues, such as had had occurred from morning to evening of yesterday, he would suffer no great risk of further infarction by being moved to a facility possibly next to the Court on the next day. That would be tomorrow.

So my final impression as of now is that he did suffer a transient and reversible episode of coronary insufficiency and myocardial ischemia, if you will, based on his underlying disease, but that this was transient, and although subject to recurrence was not a myocardial infarction which, of course, would be far more serious, and that he should remain where he was, as I said before, for 24 hours, but possibly be in a position to be removed after another 12 -- 24 hours.

THE COURT: Thank you, Doctor.

CROSS EXAMINATION

BY MR. KUH:

Q Doctor, you did learn that Mr. Pastor appeared to be suffering from some sort of a hear seizure the first thing yesterday morning, did you not?

A Yes, I did.

Q Can you tell me how you learned that?

A From you. You telephoned me.

Q About 8 or 8.15 in the morning?

A Yes, that is correct, about 8.

Q Did I implore, beg, urge you to visit him and indicate that the only way the Judge would know whether this was a valid heart seizure or not would be if you would see Mr. Pastor?

MR. TIMBERS: Objection on relevance.

MR. KUH: Your Honor has revoked Mr. Pastor's bail and has issued a warrant. I want the record to be clear. Apparently your Honor thought there was some sort of misconduct on the part of counsel in connection therewith, and I want the record clear, not from my own words, but from Dr. Texon that I implored, begged and urged him, as soon as I learned of this seizure, to please see Mr. Pastor so he could inform the Court and us so that Mr.

Pastor --

THE COURT: What time was this, Mr. Kuh?

MR. KUH: It was between 8 and 8.15, my first call to Dr. Texon, immediately after I heard from Mrs. Pastor at about 8.

THE COURT: What time was Mr. Pastor due in court?

MR. KUH: He was due at 9. It was my information that he got up and was dressing when this took place. Mrs. Pastor called me from the Summit Hotel, which is at 51st Street and Lexington Avenue.

Q Am I correct that I called you between 8 and 8.15?

A That is correct.

Q Did you indicate a willingness to go see Mr. Pastor?

MR. TIMBERS: Objection, your Honor. I don't think what Mr. Kuh asked Dr. Texon to do has any relevance to the issues in this case. The question is what was Mr. Pastor's heart condition and did it incapacitate him from appearing here in court.

MR. KUH: I'm eager to get into that. I think preliminarily --

THE COURT: I think Mr. Timbers is right.

Youdon't have any authority to direct Dr. Texon to make any examination. Your application should have been made to the Court.

The objection is sustained.

Q Then, Dr. Texon, I called you a second time, did I not?

A Yes, you did.

MR. TIMBERS: Objection.

THE COURT: The cross-examination is cut off. You may come down.

MR. KUH: May I now --

THE COURT: Would you examine the patient again this afternoon at 4.30 and let me know his condition?

MR. KUH: If your Honor please, I would like to question him about his testimony. I thought it important in light of your Honor's action on his bail that I get --

THE COURT: Come down, Doctor.

MR. KUH: I would like to examine the doctor on the conclusion that in some fashion Mr. Pastor might be able to be moved to a facility near the court, and I would like to find out what he knows about the medication available, the heart control and monitoring devices which

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are avilable --

THE COURT: You are excused, Doctor.

MR. KUH: -- the care available at that facility near the court.

MR. TIMBERS: I think there are better ways to get at that.

MR. KUH: He has given a conclusion that might be in Mr. Pastor's health interest. I suggest to your Honor I am entitled to find out the foundation of his conclusion. I would urge your Honor that I am or should be permitted to ask about some of the conclusions he expresses as to Mr. Pastor's health. Your Honor has not given us an opportunity to, as far as I know, produce evidence that may indicate Dr. Texon's --

THE COURT: We have your report which was handed up yesterday by Mr. Goldman.

MR. KUH: I would like an opportunity to produce evidence on that. I certainly would like an opportunity to cross-examine Dr. Texon, your Honor, and I have been deprived of that opportunity and I would like to make an offer of proof, if it please the Court.

THE COURT: The record is clear, Mr. Kuh --

MR. KUH: It is clear to your Honor but not to your Honor but not to me.

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THE COURT: I have ruled.

MR. KUH: I ask that I be permitted to make an offer of proof of what I believe I would be able to elicit on cross-examination of Dr. Texon.

May I make such an ofer?

THE COURT: No. I said the record was clear as of yesterday of what occurred here.

Do you have that report handed up by Mr. Goldman yesterday, Mr. Clerk?

THE CLERK: No.

THE COURT: Do you have it, Mr. Goldman?

MR. GOLDMAN: I have a copy of it. I have also a copy of the Seigel letter.

THE COURT: Mark the Kuhn letter as a report to the Court.

(Court Exhibit No. 1 was marked.)

MR. TIMBERS: May I state that I haven't

xx copies of either of those. You have taken my copy back, Mr. Goldman, and I have never seen the Seigel letter.

THE COURT: Where is the original?

Does somebody have the original which was handed Up yesterday?

MR. GOLDMAN: This was given to the Court yesterday.

MR. KUH: I wonder if the record might reflect as to the Dr. Seigel report which our office received in the mail Monday, May 17, I had indicated in colloquy with the Court on last Thursday, May 13, I believe, that we thought it extremely likely --

THE COURT: Mr. Kuh --

MR. KUH: I'm sorry.

THE COURT: You say that the Seigel letter was received in my office?

MR. KUH: No, received in our office, my law office, on Monday.

THE COURT: Let's straighten the record. You said my office.

MR. KUH: I said my office and it was my office.

If your Honor please, I started to indicate that on Thursday -- I believe that was May 13 -- I indicated to the Court a likelihood that if given the opportunity we would call one or more physicians, cardiologists from Philadelphia who had long range familiarity with Mr. Pastor's illness. The Seigel letter is in connection therewith.

Dr. Siegel did examine Mr. Pastor Thursday morning, May 13.

THE COURT: I went over that yesterday with Mr. Goldman. I told him I had already ruled on the matter as of that time and I wasn't going to rule on it again. I set forth an opinion. That report was not before me. I'm not receiving any evidence on that hearing after the hearing has occurred. I have already ruled in this case that I have had a sufficient hearing on the nature and extent of Mr. Pastor's heart condition and I am not going to hear it again.

Now the record is clear and you don't have to keep arguing with me about it. I have said that I will not hear it. I have received the doctors' reports and that is all I'm required to do. That is my view of the law and I am not going to hear it.

THE COURT: You are excused, Doctor.

(Witness excused.)

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MR. KUH: In light of the evidence that your Honor Honor took this morning it should be clear that I have an offer of proof which your Honor is not permitting me to make.

THE COURT: That is right. Your offer is clear. We heard your offer of proof yesterday and we have an indication now that you called Dr. Texon and he didn't go and he properly should not have gone. You have no authority to ask a doctor to go to the hospital for the Court and submit a report unless the Court orders it.

MR. KUH: I tried to reach your Honor's chambers. I did not ask Dr. Texon to go to the hospital. I told Dr. Texon what I had learned from Mrs. Pastor a few minutes earlier by phone.

THE COURT: And he is not Mr. Pastor's doctor. He has a right to refuse.

MR. KUH: No question that he has the right, no question, and I'm not urging that. What I do ask, your Honor, and what i ask is to be heard upon is that your Honor vacate the warrant and restore Mr. Pastor's bail condition, and I urge it on this factual basis and I would like to give your Honor the facts.

THE COURT: All right.

MR. KUH: I got a call at 8 a.m. that woke me

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yesterday morning in the village. I don't have far to travel either to work or here but because of my illness I was not going either place in the morning. I was awakened at 8 a.m. by a call from Mrs. Pastor whom I have generally found a highly controlled, unemotional woman, who was in tears and said that while he was dressing or shaving, I can't remember which, it came so quickly, but while he was getting ready for court -- he seemed fine when he got up, but he suddenly had severe pains, had taken large numbers of pills. She had administered oxygen and had him lying down but propped up so that he could breathe and she was scared as to what he was going through.

I immediately called Dr. Texon, as has been indicated, and told him what I heard and indicated that I had the impression from my familiarity with this case that the only one whom the Court would believe would be Dr. Texon; that I didn't try to direct him but I asked him whether he would be good enough to go over, and he stated that he could not.

I looked in the Manhattan phone directory for your Honor's chambers and called that number two or three times between -- I was acting quickly and I wasn't keeping a log, but between 8.15 and 8.40, and got no answer.

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THE COURT: I don't know why you expected me to be in chambers at 8.15.

MR. KUH: I did not, and I obviously am not criticizing, but I did all that I could so that your Honor would have a report by 9 and would recognize that there was no effort to frustrate the Court. I did not have your Honor's phone number or Mr. Timbers' home phone number and I know Mr. Timbers lives in Connecticut and also assumed that he was on his way, in any event, but I did not have his home phone number.

I then tried to get Dr. Kuhn. Dr. Kuhn was apparently in transit. I couldn't get him. I then called my brother, who is an internist. I asked for the names of a heart man. My brother gave me the names of two heart specialists, each of whom treated my mother less than a year ago for a heart attack. I called Dr. Uy and told him the story. He said he couldn't visit him at the time. I was afraid from the story I got that Mr. Pastor was in danger. I called the other doctor and was told by his secretary that he was on his way in from Jersey and she didn't know when he would be available.

I then called Dr. Texon a second time and I said: Please, in the interests of this patient's health,

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apart from the whole court proceeding, would he go by, and he said he could not and would not.

I finally -- I had been calling Dr. Kuhn intermittently and got him. I guess it was probably about 20 of 9, a quarter of 9 that he had gotten in. He said he would call Mrs. Pastor and would call Dr. Texon. This was all before 9. I said would he please call me back thereafter, which he did.

When he called back it was a little after 9. He said after talking with Dr. Texon and with Mrs. Pastor and in the light of the unrelieved angina, despite a large number of nitroglycerin pills, oxygen and so forth, it appeared to him that there was possibly a dangerous cardiological episode and after his conversation with Dr. Texon it was agreed that Mr. Pastor was to go to Mount Sinai Hospital where Dr. Kuhn would examine him and make the arrangement for Dr. Texon to see him subject to the Court's and the prosecutor's and everyone else's convenience, and that he had directed Mrs. Pastor to have Mr. Pastor at the hospital emergency entrance as soon as possible, and that was done. Apparently Mr. Pastor got there some time after 9 and was seen by Dr. Kuhn at 10.

I then arranged with my paralegal at my office

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to go up and see Dr. Kuhn because I knew your Honor would want an affidavit and fortunately this paralegal is a notary, so that he got from Dr. Kuhn, after he had examined Mrs. Pastor, such an affidavit and I'm told it got to your Honor some time between 11.30 and 12 yesterday morning.

Dr. Kuhn this morning, although I haven't had an opportunity to cross-examine him, has indicated there was an episode and has indicated that apart from yesterday in his considered opinion Mr. Pastor should remain hospitalized where he is at least through today subject to the later examination that your Honor is ordering.

I ask in light of those facts, I urge upon your Honor that it is crystal clear that what took place yesterday was beyond the control of anyone and I state this as a member of the bar whose credibility -- I won't pay tribute to myself, but as a member of the bar -- let it go at that -- that I had not the thinnest idea that any such episode would take place.

I saw Mr. Pastor late Monday and I will state this, your Honor, that as of late Monday to my lay eye Mr. Pastore seemed stronger than I have seen him before and I fully anticipcated he would meet Mr. Goldman here in court at 9 a.m. Tuesday for the picking of the jury

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and was shocked and dismayed by Mrs. Pastor's call at 8 a.m.

I urge upon your Honor in light of Dr. Texon's conclusion, which your Honor has, and in light of the narrative that I have just made known, and I'm certainly ready to be cross-examined on it by Mr. Timbers, that there was nothing wilful about Mr. Pastor's failure to appear in court yesterday. He had travled up from Philadelphia on Sunday and planned to be in this city all this week then back home over the weekend to see his nine-year old and then back again next week.

I urge your Honor to vacate your order issuing a warrant or asking that a warrant be issued vacating the bail condition, that you restore Mr. Pastor to bail and we proceed as we had been prior to your Honor's order of yesterday and the marshals, incidentally, whom I'm told are at Mount Sinai Hospital guarding the door therefore be relieved.

You have my word as an officer of this Court that Mr. Pastor will remain at Mount Sinai subject to this Court's order and will not be going anywhere.

MR. TIMBERS: May I be heard, your Honor?

THE COURT: Yes.

MR. TIMBERS: I believe that the letter that

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Dr. Kuhn has written to the Court dated May 18 and Dr. Texon's testimony today both confirm your Honor's belief that there was nothing serious, nothing different wrong with Mr. Pastor. Mr. Pastor does have a heart condition. He does suffer anginal pains from time to time. What he had yesterday was just another anginal pain. Both doctors confirm that fact and therefore the Court's order in directing that he be brought down here immediately was completely correct and the proper thing to do.

The Government believes, therefore, that the proper procedure to follow now that examinations have been conducted, and if Dr. Texon should find that the improvement is as expected this afternoon, that Mr. Pastor should be brought down to a place that is close to the Court House so that he can participate in these proceedings with as little inconvenience to him as possible. There is a medical facility at the Metropolitan Correctional Center.

The Government submits that Mr. Pastor should be placed in that medical facility, which is close to the courtroom. The Government will make every arrangement possible to make sure that Mr. Pastor has access to see his wife; that his doctor has access to him, and the Government would be glad to make arrangements, if the

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Court should direct, that Dr. Texon examine Mr. Pastor periodically to determine that he is healthy and able to continue with the trial.

The Metropolitan Correctional Center is just across the Brooklyn Bridge from the Beekman Hospital. If Mr. Pastor should have any difficulty --

THE COURT: Across the bridge?

MR. TIMBERS: The Beekman Hospital is not on the other side of the river but across the bridge, that is, the entrance to the Brooklyn Bridge is between the Court House and the Beekman Hospital.

THE COURT: You indicated it was on the other side of the bridge. It is on the same side.

MR. TIMBERS: I meant to say that the Beekman Hospital is very close to the Court House and Mr. Pastor would probably be closer to a hospital if he were in the MCC than he would be in any place else in New York City outside of a hospital itself.

Such an arrangement would make it possible for Mr. Pastor to return to his quarters immediately should there be a long break in the trial proceedings and it would make it easy for him to get to court. It wouldn't be necessary to make arrangements to bring him down from midtown.

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Since the evidence is that he has voluntarily absented himself from the proceedings, the Government believes that the Court has the power to direct that his bail be vacated and that he be brought down to the Metropolitan Correctional Center to insure his presence at the Court's proceedings.

So, for the reason I have indicated, I believe that the best interests of Mr. Pastore's health and the expeditious movement of this trial would be best served by bringing Mr. Pastor to the Metropolitan Correctional Center.

THE COURT: Do you want to reply, Mr. Kuh, before I rule on your motion?

MR. KUH: I do deeply. That is a new one, I guess foreshadowed by Mr. Timbers' witness, Dr. Texon.

First, Mr. Timbers said that this was simply some new heart pains. Dr. Kuhn's report and now we have no copy because we gave our original to the Cout yesterday and our copy today --

MR. TIMBERS: Here it is, Mr. Kuh.

MR. KUH: Dr. Kuhn's report states -- Mr. Timbers has just given it to me -- the third paragraph states:

"In addition" -- we are not talking about

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the subjective but objective evidence -- "there were ST segment depressions in leads V-4 through V-6 suggesting acute myocardial ischemia. These changes were not present in his last previous record."

THE COURT: For the record, that has been marked Court Exhibit 1 as of May 19.

MR. KUH: Thank you, your Honor.

Dr. Texon in the brief testimony we heard from him this morning repeated that these were new objective findings that he said later -- where they were in reversion later in the day they did exist, they were there. This wasn't simply a man experiencing pain.

Parenthetically, I would make it a subject of comment that it is easy for Mr. Timbers to say it is only a little pain. In the last three months I have gone through pain including a treatment yesterday that was as painful as anything I have ever had in my life, and I do not wish such pain on the worst enemy man could have in the world, and to have an Edward Pastor, who routinely over ten years has gotten used to anginas and has gotten relief from nitroglycerin and now relief from nitro ointment, to have been going through such pain that 20 nitroglycerin tablets and nitro gives no relief, as the doctors

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at the Ames Unit at Mount Sinai find and I think Dr. Texon's testimony that three or four morphine injections were required and given for his pain -- that is more than simply something that is in one's mind. I suggest there are new objective findings and there was clearly a pain of such depth that it was disabling.

But let me get on to the new portion that rather shocks me, and this is nothing to joke about, your Honor, but I --

THE COURT: Mr. Kuh, you have five minutes in which to complete this.

(Continued on next page.)

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MR. KUH: Your Honor, I suggest that we see Mr. Timbers' crocodile tears when he suggests it is in some way to Mr Pastor's interest to be at the Metropolitan Correction Center. I suggest to your Honor it should be clear that Mr. Pastor's wife has seen his heart condition for some ten years, she herself has pharmaceutical training, she watches him, she has seen him like a hawk. She is sensitive to his pain. She sees that he takes his medication, which is multiple, routinely, and then special -- for special pain.

She rubs the nitro ointment on his chest. She is aware of virtually his every breath. There is nobody at the Metropolitan Correction Center that will give that attention.

Secondly, Dr. Texon on February 17th testified to the impact on hear conditions and on angina pains and on ischemia and on possible infarction of tension, and I think even Mr. Timbers would have to agree that a person who is used to a life of freedom with his wife and his son once finding himself in prison is not thereby going to be relieved of tension. It obviously will aggravate and the mere prison environment will create tension that will be provocative --

THE COURT: Do you want him to stay in Mount

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Sinai throughout the trial?

MR. KUH: Either in Mount Sinai when needed or at the Summit Hotel with his wife's aid, your Honor.

THE COURT: No, he can either stay at the Metropolitan Center or Mount Sinai.

MR. KUH: If Mount Sinai will keep him, then I would say unequivocally Mount Sinai.

THE COURT: If he wants to be in the hospital, that is his choice, but otherwise it is going to be the Metropolitan Center where Mr. Timbers says there is a medical facility. It is a brand new facility, as you well know, one of the newest and finest detention centers in the United States, and it has a medical facility and the hospital is less than two blocks away --

MR. KUH: Your Honor --

THE COURT: -- from downtown, and he will stay there.

Now, if he wants to stay at his expense in Mount Sinai Hospital, he can do that, under guard, but otherwise he is going to be -- if the doctor agrees this afternoon -- brought down here and kept in the medical center until this trial is over.

MR. KUH: Well --

THE COURT: It is my view that he ought to go

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ahead with this trial and get it over with, Mr. Kuh, instead --

MR. KUH: No one quarrels with that.

THE COURT: Please don't interrupt me.

MR. KUH: I am sorry, your Honor. I apologize.

THE COURT: It is my view he should go ahead and get this trial over with Mr. Kuh, instead of dragging it out and subjecting himself to this kind of tension which you insist brings on pain.

Now, that is my view of it. The application to reinstate bail is denied and he is going to be brought down here where he can be brought to court immediately each morning instead of coming down from wherever it is he is staying, unless he wants to stay in Mount Sinai Hospital at his own expense.

MR. KUH: All right, if your Honor has given us that choice, at least to be present, until I can explore it with my client and Dr. Kuhn, he will stay at Mount Sinai Hospital.

I would urge upon your Honor that your Honor may know -- I don't know -- and I say "may know" in all seriousness -- I am not being skeptical -- whether the Metropolitan Correctional Center has heart monitoring equipment, whether it has a nurse watching this particular

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patient 24 hours a day.

THE COURT: He has that at Mount Sinai?

MR. KUH: At Mount Sinai he does.

THE COURT: He has a nurse 24 hours a day?

MR. KUH: My understanding is that the coronary unit has a group of nurses watching a small group of patients, and my understanding is the ratio is better than one nurse to one patient. That is my understanding. And, apart from that --

THE COURT: Mr. Kuh, I have ruled on your motion. It is denied.

MR. KUH: All right. Then --

THE COURT: And this afternoon, if the doctor says he is all right, as expected, he is going to be brought down to the Metropolitan Center, unless you made arrangements for him to stay in the hospital.

MR. KUH: I will make those arrangements.

THE COURT: For the duration of this trial.

Now we are going to move on.

MR. KUH: If your Honor please --

MR. TIMBERS: If your Honor please, may I make a practical suggestion in connection with the location of Mr. Pastor at the trial?

The Beekman Hospital is very near to the Court

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House. I would suggest to both the Court and Mr. Kuh that they consider, if Mr. Pastor is going to stay in a hospital, putting him into Beekman Downtown Hospital where he is very close to the courtroom. It would not involve the same long trip as it would down from Mount Sinai.

I only make that as a suggestion in order to facilitate the conduct of the trial.

MR. KUH: If your Honor please, there isn't an iota of testimony that Mr. Pastor had any trouble in any of his four trips to New York in connection with this case as far as travel, or any of his taxi trips down here.

THE COURT: Mr. Kuh, I ruled on it. I am not going to hear any more. You can take Mr. Timbers' suggestion if you like.

MR. KUH: I would simply urge, your Honor, that we have some report on the record as foundation for your Honor's ruling as to what coronary care equipment exists at the Metropolitan Correctional Center. SO far, to the best of my knowledge, absolutely none, absolutely none.

MR. TIMBERS: Your Honor, I can provide some information on this just for Mr. Kuh's assistance in

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in deciding where to place his patient.

The Metropolitan Correctional Center has a working arrangement with the Beekman Downtown Hospital and with Bellevue Hospital. They have, in addition, their own medical facilities.

However, if Mr. Kuh should desire to place Mr. Pastor in the Beekman Downtown Hospital, the marshals would pick Mr. Pastor up every day and bring him the short distance to the court under a workir arrangement that the Metropolitan Correctional Center has with the Marshal's office and the Beekman Downtown Hospital.

MR. KUH: I respectfully urge, your Honor --

THE COURT: All right, you have that for your information, Mr. Kuh.

MR. KUH: I respectfully --

THE COURT: Now, I am going to bring in the jury and let them go home until tomorrow morning at 9 o'clock.

(Jury present.)

THE COURT: All right.

Do all the jurors have their proper seats now? Where are the alternate jurors? Are they sitting at the end?

THE CLERK: Alternate Juror No. 1 is in the

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first seat in the first row over there.

Alternate Juror No. 2 is in the back -- 1 and 2.

THE COURT: Suppose we just call the roll on the jurors and make sure they are in the right seats.

(Jury roll call.)

THE COURT: All right.

Ladies and gentlemen, I am sorry for the delay in getting started this morning, but it now appears that we are not going to be able to proceed with the receipt of testimony today. We are going to have to recess with respect to the jury until 9 o'clock tomorrow morning.

Now, with respect to that, I want to give you a further instruction, and that is that during the course of the trial there are apt to be other times when we have delays like this and the reason for it is that I have legal matters to discuss with the lawyers out of your presence and it cannot be avoided and you will have to be sitting in the jury room.

In further connection with that, I would like to point out that you will have to be patient. As you probably realize, patients is an important virtue in seeing that justice is done in any case. We cannot avoid the delays which occur during the course of any

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trial because we do have to discuss the legal matters out of the presence of the jury. That is a requirement. That is what we have been doing this morning.

And it now appears that we will not be able to proceed with the actual receipt of testimony. So rather than let you sit here the rest of the morning, we are going to excuse you now until 9 o'clock tomorrow morning.

I want to caution you further, as I did yesterday, that you are not to discuss the case among yourselves or with anyone else until you have finally retired to the jury room to deliberate.

All right. You are excused now until 9 o'clock tomorrow morning.

Everyone in the courtroom remain seated until the jurors have left.

(The jury left the courtroom.)

THE COURT: Mr. Timbers, during the course of the trial do you anticipate any need for that blackboard?

MR. TIMBERS: Your Honor, I was thinking about using it in connection with my opening statement.

THE COURT: Well, all right. I was trying to make more room in that aisle.

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MR. TIMBERS: I would be glad to have it placed in another room while I am not using it.

THE CLERK: I can put it in the back of the courtroom, your Honor, which is behind one of the benches.

THE COURT: All right. In that way we can move these counsel tables a little to my left so that we can have the lawyers in the case as far removed from the jury as possible so that during the course of their off the record conversations the jurors are not apt to overhear it.

Now, gentlemen, as you see, this is a small courtroom and you are very near to the jury. You have a right to confer, but you do not have a right to confer in such a manner that it will be overheard by the jurors. So keep your voices down during your conferences in this small courtroom.

There is not to be any extrajudicial communication with the jurors such as we had yesterday in this case. So please bear that in mind.

All right.

Now, do we have some other matters? Are we ready to proceed with the hearing that we commenced the other day, Mr. Kuh?

MR. GOLDMAN: Your Honor, may I be heard for

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a moment?

THE COURT: Yes.

MR. GOLDMAN: Your Honor, so we do not have a hassle tomorrow occurring let me know now. I certainly will oppose a blackboard on opening statement, the use of a tangible visible aid prior to the time of offering evidence is highly irregular and improper and I do not want to make an issue of it tomorrow.

THE COURT: Mr. Timbers.

MR. TIMBERS: I do not intend to use a chart or other piece of evidence that is prepared, but as I stated, during my opening I intend to use a piece of chalk to make an appropriate mark on the blackboard. This is a standard procedure that is frequently used in this court.

I do recognize that it would be improper for me to come in here with a prepared chart that would demonstrate my case when there was no evidentiary basis for that, but after I have said something to the jury I believe that it is proper for me to make a mark on the blackboard that records the statement I made to the jury.

THE COURT: I don't understand. You have to be more specific. You are going to have something written on the board which you will then check off?

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MR. TIMBERS: No, no. When I start my opening statement the blackboard will be blank. As the opening statement progresses I will write words, diagrams, what-have-you, on the blackboard.

THE COURT: I see.

MR. TIMBERS: I have done this in several opening statements, your Honor, without any objection.

In the United States versus Sperling before Judge Bonsal both the Government and the defendants used the blackboard. I believe there are several other cases that don't come to my mind right now where I have used a blackboard on the opening statement.

THE COURT: Well, you are going to write down the names of the drugs, for example, which are unfamiliar terms, is that it, that kind of thing?

MR. TIMBERS: Yes.

THE COURT: All right. If it is limited to that, to wriging the name or the names of the two drugs involved here, which would be unfamiliar to the jurors, that limited demonstration in the opening statement will be permitted, but nothing beyond that.

MR. TIMBERS: Just to make it clear, that is the sort of thing I intend to do. I would probably also indicate the names of the companies and things that are

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unfamiliar to the jury.

THE COURT: I think I gave them the names of the companies in the voir dire yesterday so you don't have to write that; just the names of the drugs, so when they hear it they can understand what the word is. Perhaps if they see it written out, that would help.

MR. TIMBERS: I am considering explaining to the jury how certain of the transactions in this case operate, and I thought that I would, after I had explained that Mr. Pastor, for instance, placed the order, I would write Mr. Pastor's name down. And then after I explained that he placed the order with Wingate, I would write Wingate down and --

THE COURT: Well, that is going too far, I think. As the defense counsel point out, the purpose of the opening statement is to give the jurors a kind of bird's-eye view of what you expect to prove. That sounds to me like what you would do in closing argument based on the evidence already adduced at trial.

MR. TIMBERS: I will be glad to abide by your Honor's ruling. It is a very simple thing and I don't think there is any dispute that Mr. Fernald and Mr. Pastor and Mr. Weiner placed their orders with Wingate, which in turn placed the orders with Garden Laboratories, and

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also the defendants placed orders with --

THE COURT: I see defense counsel getting up. There is not going to be any stipulation I gather here. So I suggest to you you just take your time and make an opening statement to the jury without going into too much detail on the blackboard other than putting on the blackboard the names of these two drugs which are obviously unfamiliar to laymen in the spellings and pronunciation. If they see it on the blackboard they will be able to hear it better when said during the course of the trial because I gather there would be constant reference to that, or any other unfamiliar term can be put on the board. However, no company's name here is so unfamiliar that the jury couldn't grasp it when hearing it.

MR. TIMBERS: I will be glad to abide by the Court's ruling.

MR. KUH: May it please the Court, before we proceed further I have an oral motion to make.

I move that the charges in the indictment against defendant Edward Pastor be dismissed at this time because of the deprivation of his constitutional right against cruel and unusual punishment. And I suggest to your Honor that your Honor now, in advance of trial, and for no reason whatsoever, because he has appeared whenever

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physically able, by saying he must either go to a correctional facility or remain in a hospital is punishing him for his illness. That is contrary to the Robinson case decided by the U. S. Supreme Court. It constitutes cruel and unusual punishment. It deprives him of his constitutional rights under our bill of rights.

I suggest with great respect to the Court it is being arbitrary, there being no possible showing that Mr. Pastor's tension, which is the provocative cause, provocative item in his heart seizures will be eased if he is in a correctional facility as opposed to the status when he is with his wife who, with her pharmaceutical training, with her knowledge of them, with the fact that she has been administering to him for some ten years would clearly give better care.

And I therefore respectfully suggest to go ahead with your Honor's plan that he be either in a correctional facility or in a hospital at expense to himself while he remains hospitalized I suggest constitutes cruel and unusual punishment and I ask that the indictment be dismissed or that your Honor reconsider your position, particularly in the light of the Robinson case which indicates the impropriety, indeed the unconstitutionality of punishing for illness, which is what -- in Robinson

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it was at least during the trial. Here it is in advance of trial and it is punishing him for a serious heart condition, acknowledged by the Government's expert Dr. Meyer Texon.

THE COURT: The motion is denied.

The defendant's bail is revoked for failing to appear when required to appear yesterday morning.

MR. KUH: If your Honor please, I think the reasons have been fully gone over and I think your Honor is arbitrary and capricious.

THE COURT: You don't have a right to comment on my ruling after I make it, Mr. Kuh.

MR. KUH: If your Honor please --

THE COURT: You said there were some discovery matters not completed and we will take those up. If you are ready we will proceed with the hearing. If not, we will adjourn to tomorrow morning at 9 o'clock.

MR. KUH: Before we proceed with the hearing, there are incomplete discovery matters started on Monday pursuant to your Honor's direction in the presence of the defendant.

I believe we did except yesterday, your Honor, to the jury selection in the absence of the defendant and I certainly will except to proceeding with the Miranda

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hearing which does require his presence.

MR. TIMBERS: May I say on that point, your Honor, that yesterday morning Mr. Kuh was in constnt contact with Mr. Fiske of our office and Mr. Abr-nowitz, the head of the Criminal Division, and during those conversations Mr. Kuh indicated that his client would be willing to waive his presence at the jury selection.

THE COURT: Yes.

MR. KUH: Not true, absolutely false.

MR. GOLDMAN: Your Honor, I confirm it's 100 per cent untrue.

MR. KUH: I ask for a hearing and I ask that Mr. Fiske come down.

THE COURT: First of all, you are going to have to elect between yourself and Mr. Goldman which one of you is going to try this case.

MR. KUH: Mr. Goldman is going to try it.

THE COURT: The reporter cannot get it when two lawyers jump up at the same time as you and Mr. Goldman did and cut across Mr. Timbers.

Which one is going to try the case?

MR. KUH: We made clear on Thursday at the pretrial hearings that I could not continue. Mr. Goldman will try it.

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MR. GOLDMAN: I have one motion to make with regard to the trial itself.

THE COURT: Let us finish with this matter.

Mr. Kuh, the record will disclose that last Thursday you were ready to waive Mr. Pastor's presence with respect to the pretrial hearings.

MR. KUH: Not true, your Honor.

THE COURT: Which I denied and ordered him to appear Monday morning, which he then did. Isn't that so?

MR. KUH: No. The record will disclose I said I would waive his presence at the hearing at which Mr. Timbers was to testify on the grand jury because he would have no knowledge and couldn't help in any fashion. And on that I indicated in the interests of moving ahead and saving him coming to New York any sooner than needed I would waive his presence at the Wade hearing at which his contribution would be minimal.

I indicated I would need his presence at the Miranda hearing, and so it was my request to your Honor on Thursday that you first have the so-called Timbers grand jury hearing, next the Wade hearing and last the Miranda hearing. We are now in the midst of the Miranda hearing and I do need his presence at the Miranda hearing.

THE COURT: All right. We will postpone that

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until he comes, but the trial is going to go ahead. We don't have to dispose of that matter before the trial.

MR. KUH: I wonder if your Honor would out of courtesy -- and that is the only basis for asking this, my own illness which makes it impossible for me to continue the trial -- would schedule the continuation of the Miranda hearing and the Wade hearing for a certain date so that I don't have to come down here each day and sit for four hours of the trial which because my health is such I cannot do. That is my reason for getting out of the trial, your Honor.

THE COURT: Well, we will let you know as soon as we can when the hearing will continue.

MR. KUH: Then I gather yesterday something was said about my convenience, your Honor, and my convenience has nothing to do with it. I understood on Monday that I was not to be here yesterday unless your Honor during a recess directed it. I will not be here until your Honor indicates to Mr. Goldman that you are going ahead with the Miranda hearing and then we will have the Wade hearing.

Am I correct in that understanding?

I mean no discourtesy to the Court. If the Court tells me to show some place, regardless of my health

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I will be there. But, on the other hand, I ask out of simple courtesy for the condition I am suffering from that your Honor not have me here needlessly.

THE COURT: Well, yesterday when we tried to find you Mr. Goldman, as the record will disclose, said he didn't know where you were. He didn't know whether you were home sick or at your office and he said he would try to find you.

MR. KUH: Yestereay I was -- sorry.

THE COURT: The record will disclose that is what he said. Now, you have a transcript of the record. Read it. That is what he said when we recessed at 12.30. In fact, it was 12.10 as we took 20 minutes to argue about it, about whether we would go ahead with the hearing. He claimed he couldn't go ahead, that only you could go ahead, and he didn't know where you were.

MR. KUH: I think one of the problems is that Mr. Goldman has come late to this.

THE COURT: Mr. Cooper was there and he could have gone ahead with it.

MR. KUH: Mr. Cooper had called me at one point during the early morning after your Honor had ordered the marshals out for Mr. Pastor and I told Mr. Cooper that I would stay home until one o'clock and then leave at

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one o'clock for the office.

THE COURT: He didn't convey that information to Mr. Goldman.

MR. KUH: I assume yesterday was a busy day --

THE COURT: And he was going in and out of the courtroom yesterday morning making telephone calls all morning.

MR. KUH: May I understand, your Honor, that I am not to be here until your Honor indicates to counsel the previous day that I am not to be here?

THE COURT: Yes.

MR. KUH: Thank you.

THE COURT: If we have a lull in the trial we will take it up before the evidence is actually introduced, but we will go on with the trial per se.

Do you expect to put in the Wade problem early in the trial?

MR. TIMBERS: Your Honor, it would be in the last part of the trial. Similarly, Mr. Pastor confessions do not come until the end. I will not make mention of either in my opening statement. I will simply tell the jjry there is other evidence, but will not describe it.

MR. KUH: If your Honor please -- sorry.

THE COURT: YOu don't even have to make that

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reference.

MR. TIMBERS: That will refer to other indefinite evidence.

THE COURT: I told you at the beginning you are not putting on your case. You are only giving them a view of what you intend to prove. You don't have to make reference to any particular item of evidence.

MR. KUH: I think the record should be crystal clear, your Honor, that I had one conversation with Mr. Fiske I believe yesterday, though it may have been Monday, and several conversations with Mr. Abramowitz --

THE COURT: Mr. Kuh, I am not going to hear it because everything Mr. Timbers says you deny. And I am not going to have a hearing on that, to determine who is telling the truth and who is not.

Mr. Timbers hasn't said anything here that took place out of court that you haven't denied, and the record will disclose that. So I am not going to sit here and listen to each one of you on that. We have to move on.

What discovery matters have not been turned over?

MR. TIMBERS: May I say in connection with that, your Honor, that I turned over to Mr. Goldman

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yesterday all the Fernald 3500 material. I marked it, but I don't have the exhibits here, so I will put them on the record by tomorrow. However, the defendants do have all the 3500 material.

THE COURT: What witnesses are there? Fernald and who else?

MR. TIMBERS: Just Fernald. Fernald, as I have said several times, is the Government's first and main witness and that 3500 material has all been turned over to the defendants -- both to Mr. Goldman and to Mr. Sparks.

MR. KUH: If your Honor please, before we recess, just so this record can be clear, it is my understanding that in no fashion yesterday did Mr. Goldman and Mr. ooper that I know of my own knowledge and in no fashion did I waive the right of the defendant to be present at the jury selection.

Now, defense counsel could be mighty cute and say there is no waiver, and in effect, your Honor, the U. S. Attorney proceeds at their own risk. I will make it clear now we move for a mistrial. There will be no claim of double jeopardy that the defendant wasn't here during the jury selection, and we, therefore, move for a mistrial.

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We do not consent. We do not waive and never did in any way, shape or form.

And Mr. Goldman is now showing me the minutes of yesterday at page 157 of which Mr. Cooper says:

"If your Honor please, before we proceed, I would make the same objection to having to go forward without Mr. Pastor at this time. I believe he has a right to be here until it is determined --"

-- and then his conversation is interrupted.

So I make it clear we in no fashion consent to this jury selection in the absence of Mr. Pastor. I will not put your Honor on the horns of a dilemma. I will formally move for a mistrial and hence there will be no double jeopardy if your Honor wishes to start over again, but, if not, obviously that is up to your Honor and the U. S. Attorney.

MR. TIMBERS: May I make two points in respect to that, your Honor? First of all, in reconstructing my recollection about the waiver of the jury trial conversation, I am not suggesting in any way anybody said this on the record in court. I think, to make the record clear, though, that my best recollection now is that Dr. Texon reported Mr. Kuh's comment to me either as being something Mr. Kuh said to Dr. Kuhn, or something

Mr. Kuh said to Dr. Texon directly.

The second point --

MR. KUH: May I ask what comment that was? I missed the beginning.

MR. TIMBERS: That you were willing to waive the selection -- the defendant Pastor's presence at the selection of the jury.

MR. KUH: Just so I can be clear, that is not something I said to Fiske or Abramowitz, but now something I said to Dr. Texon?

MR. TIMBERS: I never said it was something you said to Abramowitz.

THE COURT: In any event, I ruled yesterday and rule again today that the defendant voluntarily absented himself from this trial, and in that case the Court is permitted to go ahead without the defendant. That is what happened yesterday.

MR. TIMBERS: Your Honor, may I make one further point, which is really a question?

Does the counsel for Mr. Weiner also join in that motion for a mistrial?

MR. GOLDMAN: What was that?

(Pause.)

MR. SPARKS: Your Honor, on behalf of the

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defendant Weiner I would join in the motion for a mistrial.

THE COURT: All right. The motion is denied and the Court has ruled that the defendant Pastor voluntarily absented himself from the trial and, as I said yesterday morning, and repeat now, this is a part of a strategy on the part of defense counsel to obstruct and delay the trial. And that is thoroughly supported by the record in this case.

MR. KUH: If your Honor please, on a point of personal privilege, I resent that remark. I have been at the bar almost 30 years and I haven't done anyth ng disingenuous in this courtroom or any courtroom, and neither your Honor nor anyone else has the right to accuse me of dishonesty.

THE COURT: I have said it, and I will repeat it. And if you raise your voice at me once more, you are going to have to get a lawyer, Mr. Kuh. I warned you about that. I am not here to argue with you and you don't have any right to raise your voice and scream at me.

I ruled that yesterday. I rule it again. This is a deliberate design on your part to obstruct and frustrate this trial and to keep Mr. Pastor from going to

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trial. And, as I said yesterday morning, I may be overruled by a higher court, but that is my ruling and I repeat it.

You are engaged in an obstruction of justice as far as I can see just trying to keep this trial from going ahead.

MR. KUH: Without raising my voice, I would like to state --

MR. GOLDMAN: Your Honor --

MR. KUH: Without raising my voice, I would like to state on the record that her Honor has absolutely no basis for anything she said and walked off the bench without hearing the response.

(Adjourned to Thursday, May 20, 1976, at 9.00 o'clock a.m.)

WITNESS INDEX

Name	Direct	Cross	Redirect	Recross
Meyer Texon	192	196		

EXHIBIT INDEX

Court	Identification	In Evidence
1		200

File

Cfm

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK



UNITED STATES OF AMERICA :

-v- : 76 CR. 253

EDWARD PASTOR and MARTIN WEINER, :

Defendants. : 4/4/76

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CONSTANCE BAKER MOTLEY, D. J.

MEMORANDUM OPINION

Defendants Edward Pastor and Martin Weiner stand indicted on one count of conspiring to violate Sections 812, 841(a)(1), 843(a)(2), and 843(a)(3) of Title 21, United States Code, and four counts of violating Section 843(a)(3) by allegedly illegally obtaining various quantities of the drugs phendimetrazine and phentermine. On this motion, they seek to dismiss the indictment pursuant to Rule 12, Fed. R. Crim. P., on constitutional grounds. However, as the court has previously ruled, the motion is denied, for the reasons more fully set forth herein.

Defendants' arguments are primarily directed at the statutory scheme embodied in 21 U.S.C. §§ 811 and 812, both on its face and as it operated to effectuate the scheduling of phendimetrazine and phentermine as "controlled substances" within the meaning of the Drug Abuse Prevention and Control Act of 1970 (Drug Abuse Act), 21 U.S.C. §§ 801 et seq.[1/] Briefly summarized, the arguments are as follows: (1) in giving to the Attorney General the authority to add new drugs to the lists of controlled substances which it initially enumerated, the Congress undertook an illegal delegation of legislative power to an officer of the Executive branch of the Government; (2) such a delegation creates an unwise and improper concentration of power in the hands of the Attorney General which is

subject to abuse; (3) the standards promulgated by Congress to guide the Attorney General in the exercise of his authority are so vague as to give no guidance to the delegee; and (4) assuming, arguendo, the validity of the delegation effected by the statute, the Attorney General abused his discretion in scheduling phendimetrazine and phentermine by (a) improperly considering factors extrinsic to the statutory scheme and (b) failing to consider all the factors which the statute requires him to consider in making his decision. These arguments will be treated seriatim.

I

Defendants' first contention, of unlawful delegation, is premised upon the authority given to the Attorney General of the United States by 21 U.S.C. § 811 to add to the schedules of controlled substances, enacted by Congress and found in 21 U.S.C. § 812, certain drugs or other substances which he finds have a potential for abuse. Inasmuch as other sections of the Drug Abuse Act set forth serious criminal penalties for unauthorized dealings in controlled substances, defendants argue that this grant of scheduling authority constitutes an unconstitutional delegation of legislative power, enabling the Attorney General to render criminal conduct which had previously been innocent.

Before dealing with the specific statutory mechanism established by the Drug Abuse Act, it should be noted that the doctrine of unconstitutional delegation has been one of limited vitality and infrequent application in the federal courts in recent years. See Jaffe, Judicial Control of Administrative Action 69-72, 85 (1965); 1 K. Davis, Administrative Law Treatise §§2.01, 2.02, 2.06 (1958); Gellhorn and Byse, Administrative Law 60-65 (1970). Only twice has the United States Supreme Court invalidated congressional delegations to governmental authorities. Panama Refining Co. v. Ryan, 293 U. S. 388 (1935); Schechter Poultry Corp. v. United States, 295 U. S. 495 (1935); Davis, supra, §2.06. Both cases "dealt with delegations of power to make federal crimes of acts that never had been such before and to devise novel rules of law in a field in which there had been no settled law or custom." Fahey v. Mallonee, 332 U. S. 245, 249 (1947). Although transactions in the particular drugs here involved have apparently not been previously illegal, it is clear that drug possession and use has long been an area involving criminal sanctions.

To say that Congress cannot delegate its power to legislate, by virtue of the separation of powers mandated by the United States Constitution is merely to declare an axiom which is of little assistance in deciding the merits of a particular statutory scheme. The Supreme Court has indicated

that a delegation is ". . . constitutionally sufficient . . . if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of the delegated authority." American Power Co. v. S.E.C., 329 U.S. 90, 105 (1946). What is important is that the authority given to an officer of the Executive branch be guided and circumscribed by criteria which are intelligible both to the officer involved and to a court which might be reviewing the administrative decision at a later date. Thus, the propriety of a delegation is usually dependent upon the adequacy of the statutory standards promulgated to guide the administrator (as defendants argue in their third point).

However, defendants do not argue, on this branch of their motion, merely that the statutory standards are unduly vague or meaningless so as to vest an uncontrolled discretion in the hands of a government officer. Rather, they stress that the grant to the Attorney General of the authority to "create new crimes" by adding new substances to the schedules of controlled substances is invalid, irrespective of the quality of the criteria governing the exercise of his discretion. In so arguing, they explicitly disclaim, as they must, any contention that Congress cannot authorize administrative agencies (including Executive departments) to promulgate regulations necessary or relevant to their effective

functioning, violation of which would constitute a criminal offense. United States v. Grimaud, 220 U. S. 506 (1911). However, they attempt to distinguish the delegation at issue here from that involved, hypothetically, in a grant of power to the Secretary of Health, Education, and Welfare, which would, in their view, be "at least arguably necessary to the exercise of reasonable controls over pharmaceuticals." The critical distinguishing factor, they argue, is that the power to schedule drugs is here vested in the nation's chief prosecutorial officer.

This latter contention appears to be without merit, and is certainly irrelevant insofar as the question of the validity of the delegation is concerned. Since the essential evil of excessive delegation is that Congress thereby abdicates its legislative responsibility to a member of the Executive branch, the identity of that official and the nature of his duties appear irrelevant to resolution of the delegation questions.

As defendants frankly admit, their contention that this delegation is impermissible by virtue of the office of the delegee, i.e., the Attorney General, rather than his mere position in the Executive branch of the government presents this court with a question apparently of first impression. Two other courts have considered the validity of a closely similar delegation of scheduling authority to the Secretary of Health, Education, and Welfare previously found in 21 U.S.C. § 321(v)

"consider" the factors there prescribed. Where the

(3).[2/] White v. United States, 395 F.2d 5 (1st Cir. 1968), cert. den. 393 U. S. 928 (1968); Iske v. United States, 396 F.2d 28 (10th Cir. 1968). In both cases, the courts upheld the delegation effected by the questioned statute, with a discussion which mainly considered the adequacy of the standards to guide the Secretary's decision to classify certain drugs—a discussion more appropriate to consideration of defendants' third contention, infra. It is certainly true that the statute involved in those cases, the Federal Food, Drug and Cosmetic Act, provided for the Secretary's referral of possible criminal violations of the Act to the Justice Department for prosecution, rather than for institution of criminal proceedings by the Secretary himself. However, although defendants stress this distinction, they offer no pertinent authority to support their contention that it is of vital significance. Certainly there is nothing in either White or Iske which deals with this question, because it was not before either court. In fact, defendants have cited only one case squarely holding that a delegation of the type effected by the Drug Abuse Act is impermissible. In Howell v. Mississippi, 300 So.2d 774 (Miss. 1974), the Supreme Court of Mississippi held unconstitutional a portion of a state statute closely modeled on the federal legislation here in question, 21 U.S.C. § 811. The Mississippi statute had permitted the State Board of Health to reschedule substances administratively, much as the Attorney General does

under the federal statute, and the petitioner in that case was subject to a higher criminal penalty for his possession of amphetamines because the state agency had transferred that drug from state Schedule III to state Schedule II.

Faced with those circumstances, the state court squarely held (at 781) that "the authority to define crimes and fix the punishment therefor is vested exclusively in the legislature, and it may not delegate that power either expressly or by implication...." In its view, the action of the state administrative agency in rescheduling the drug, and thereby increasing the criminal liability for unauthorized possession thereof, "infringe[d] on the separation of the powers of government and is prohibited."

However, as the Government properly points out, the Mississippi constitution, on which the court's decision was predicated, appears to embody a stronger anti-delegation policy than the federal Constitution. Not only does it provide, in Article I, Section 1, that the powers of the government are to be divided in tripartite fashion as in the United States Constitution, but it also goes on to provide, in Article I, Section 2, that "No person or collection of persons, being one or belonging to one of these departments, shall exercise any power properly belonging to either of the other. . . ." Since the Mississippi court cited both

provisions in concluding that the delegation in the state statute offended the principle of separation of powers, it seems entirely possible to conclude that the conjunction of these provisions was especially persuasive in that case.

Even if this constitutional peculiarity were not involved in the Howell case, however, this state precedent is, of course, not binding on the federal courts. And, as several authorities have noted, the anti-delegation doctrine has retained much greater vitality in the state courts generally than it has in the federal courts. Davis, supra, at § 2.07; Gellhorn and Byse, supra, at 68; Jaffe, supra, at 73. Indeed, the only two federal cases cited by defendants which dealt directly with challenges to the validity of 21 U.S.C. § 811 found it unnecessary to address the arguments directed toward the delegation of authority effected by that statute. United States v. Westlake, 480 F.2d 1225 (5th Cir. 1973); United States v. Jones, 480 F.2d 954 (5th Cir. 1973), cert. den. 414 U. S. 1071 (1973). (In each of these cases, the drug involved had been scheduled by Congress itself when the Drug Abuse Act had been originally enacted, so that the defendants had not been affected by the delegation provisions of the legislation.)

There is, thus, no pertinent federal authority squarely invalidating the delegation here at issue, and the court does not find the Howell case persuasive, for the reasons set forth, supra. Leaving aside consideration of the adequacy of the criteria to guide the delegee's action, whatever constitutional infirmity may exist in this delegation to the Attorney General must be found by examination in light of the due process clause, since it appears to this court irrelevant, in determining the permissibility of the delegation, whether the delegated authority is vested in one officer of the Executive branch or another. The only relevant inquiry is whether the power should be exercised outside the Legislative branch at all.

II.

The due process argument is a superficially appealing one. Defendants lay great stress upon the fact that it is the Attorney General, the nation's chief prosecutor, to whom the statute entrusts the authority to "criminalize previously innocent conduct". The specter they raise by implication is serious indeed—that of a prosecutor creating crimes by fiat and then bringing to bear the severe penalties provided by statute in pursuit of his own personal

predilections. See Smith v. Goguen, 415 U. S. 566, 575 (1974). Pointing out that certain recent Attorneys General have been the subject of criminal prosecutions, they argue that this statute presents the opportunity for serious abuse of governmental authority and official discretion.

This frightening scenario is, fortunately, not a realistic possibility due to various statutory safeguards enacted in response to similar concerns which were voiced during Congressional consideration of the Drug Abuse Act. See H. R. Rep. No. 91-1444, Sept. 10, 1970 quoted in 1970 U. S. Code Cong. and Admin. News, p. 4589. The Attorney General's discretion is quite thoroughly circumscribed by procedural requirements.

While the Attorney General may, by rule, add a drug or other substance to the schedules enacted by Congress in § 812 of Title 21, he may not do so until he (a) finds that such a drug has a "potential for abuse" and (b) makes, with respect to such a drug or other substance, the findings prescribed by subsection (b) of section 812 for the schedule in which such drug is to be placed. 21 U.S.C. § 811(a). Any such rule must be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by the Administrative Procedure Act, 5 U.S.C. §§ 551, et seq.

In making the finding of "potential for abuse" and in making the findings required by § 812, the Attorney General must consider eight factors outlined in § 811(c).[3] By virtue of § 811(b), however, the responsibility for investigating these factors is shared with the Secretary of HEW, in that, prior to adding or removing a substance from the schedules of § 812, the Attorney General must request from the Secretary a scientific and medical evaluation of the drug, along with his recommendations as to whether such drug should be controlled and, if so, under what schedule. In making his recommendations, the Secretary must consider all of the scientific and medical factors listed in § 811(c) and any scientific or medical considerations involved in the remaining factors.

Significantly, "[t]he recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance." Section 811(b). Thus, the Attorney General may not arbitrarily schedule a drug if the Secretary finds that there is no scientific basis for doing so.[4] Moreover, his decision to schedule a drug is subject to judicial review pursuant to § 877 of Title 21.

The legislative history of the Drug Abuse Act makes clear that the hearing and judicial review provisions were added to the Act with the express purpose of checking the Attorney General's powers: "The procedure which the Attorney General must then follow to control a drug involves rulemaking proceedings on the record after opportunity for a hearing. This provides opportunity for consideration of the view of persons who would be adversely affected by control of a drug, with judicial review available thereafter. . . ." H. R. Rep. No. 91-1444, supra, at 4589.

It seems clear that the restrictions upon the Attorney General's power to "create new crimes" by adding to the lists of controlled substances are sufficient to ensure that his authority will be exercised in a fashion which is both subject to public and judicial scrutiny and also grounded in scientific evidence. To suggest that this authority, which cannot be exercised without the concurrence of the Secretary, amounts to an unbridled power in the nation's chief prosecutor such as to deny the defendants their right to a fair trial and to due process of law is to engage in wholly unwarranted hyperbole. Certainly the facts of this case reveal no impropriety or abuse of power such as that suggested by defendants. As Professor Davis has

noted, "[t]he principle whose soundness has been confirmed by both early and recent experience is the principle of checks. . . . We have learned that danger of tyranny or injustice lurks in unchecked power, not in blended power." Davis, supra, § 1.09.

III

The more substantial objection which defendants raise to the delegation effected by the Drug Abuse Act is that the guidance provided by the statutorily prescribed criteria found in § 811(c) is inadequate to circumscribe the Attorney General's discretion. They more specifically argue that the standards are so vague as to render a conviction for a crime under the Act violative of due process. With this contention the court cannot agree.

The factors which both the Secretary and the Attorney General must consider in making the scheduling decision have been previously set forth.[5/] Defendants direct the larger part of their criticism at the "potential for abuse" factor, arguing that it is nowhere defined in the statute and is so vague as to be totally devoid of intelligible content.[6/] Since the statute mandates that both the Attorney General and the Secretary[7/] consider the "actual

or relative potential for abuse" of a drug proposed for scheduling, and since the Attorney General must make ultimate findings concerning the drug's potential for abuse,[8/] this factor is of critical importance in the statutory scheme and was so regarded by the authors of the legislation.[9/]

In this court's view, the legislative history of the Act provides ample guidance for evaluation of the potential for abuse of a drug proposed for scheduling. The House report indicates that the Attorney General should consider whether the drug is being taken in amounts sufficient to create a hazard to health or safety; whether there is significant diversion of the drug from legitimate drug channels; whether individuals are taking the drug on their own initiative without advice from a doctor; whether the drug is a new drug closely related to a drug that has already been listed as having a potential for abuse; and whether there has been misuse of the drug resulting in injuries and suicides.

As noted in the House report, many of these criteria were the same as those which had previously been utilized by the Secretary of HEW to make a similar determination of "potential for abuse" under the Food, Drug and Cosmetic Act. And it was that same standard of "potential for abuse"

which was sustained in White and Iske, supra, after consideration of the legislative history, against charges that it was a standard so vacant as to render void the statutory delegation of scheduling authority. As noted by the court in White,"[o]ther schemes much broaded in scope and with less guidance to administrative agencies have been countenanced by the Supreme Court. [citations omitted]" 395 F.2d at 9.

While it seems virtually inevitable that differences of interpretation of all the statutory criteria will arise, that vice seems inherent in any system of standards which is proposed to guide an administrator's actions. The necessary inquiry must be whether the standards are so totally devoid of meaning as to form no meaningful restraint on the action of the delegee, to give him no inkling of the legislature's intent. In view of the broad standards which have previously been sanctioned by the courts,[11/] this court cannot conclude that the standards of the Drug Abuse Act are impermissibly vague. As the Tenth Circuit noted in Iske, supra, at 31:

> "In the area of drug regulation, delegations have been generally sustained despite broad standards of discretion. 1 Sutherland, Statutory Construction § 317 (3rd ed. 1943).

> This must necessarily be so, for with new drugs being discovered and introduced at an unprecedented rate, it would be impossible for Congress to determine beforehand those drugs to which it wishes a particular policy to be applied and to formulate specific rules for each situation."

IV

Defendants' final contention is primarily a factual one. Based upon examination of extensive documentary material produced by the Government prior to trial, defendants contend that, even assuming the sufficiency of the standards provided by the Congress to guide the Attorney General's decision to schedule drugs, he in fact failed to consider those factors in making the decision to schedule phe dimetrazine and phentermine. For the reasons set forth, infra, the court finds this argument unpersuasive.

As indicated previously, both the Attorney General and the Secretary of HEW bear some responsibility in the process which leads to the decision to classify a drug as a controlled substance. The Attorney General presently

delegates his authority to the Administrator of the Drug Enforcement Administration, and previously, at the time of the classification of phendimetrazine and phentermine, he had delegated his authority to the Director of the Bureau of Narcotics and Dangerous Drugs (the Director). 28 CFR § 0.100. The Secretary has delegated his authority to the Assistant Secretary for Health. 21 CFR § 2.120.

The statute clearly requires that both the Secretary and the Attorney General must consider the factors set forth in § 811 (c).[12/] However, the role of the Attorney General in considering the scientific and medical factors is somewhat ambiguous, since § 811(b) provides that the Secretary's recommendations to the Attorney General as to scientific and medical matters shall be binding on him. The only reasonable interpretation reconciling these provisions must be that the Attorney General, while not obligated to investigate the scientific and medical matters de novo, must take into account the Secretary's findings in making his scheduling decisions, and may not predicate his decisions solely upon evidence of abuse history.

This distinction in agency functions goes far in explaining the seeming paucity of medical and scientific evidence which defendants obtained pursuant to their discovery requests. By letter of October 17, 1975 to Richard Lebovitz, an attorney in the Office of the Chief Counsel of

the Drug Enforcement Administration[13/] (DEA) to whom defendants had been referred by the prosecutor in this case, defendant Pastor's counsel requested, inter alia, "the report of the Secretary of Health, Education and Welfare [concerning phendimetrazine and phentermine] and any accompanying documentation"; "all underlying data on which that report was based"; "any and all reports, evidence, or other materials submitted to the Attorney General"; and "all underlying data on which those reports, evidence or materials were based". After receiving some 4800 pages of material, defendants were informed, by letter from Assistant United States Attorney John Timbers dated December 22, 1975, that "the documents you received last Friday complete the D.E.A.'s response to your request for documents [previously outlined]."

After examining the material thus obtained and, properly, sorting out those documents which were obviously obtained after the date of the Attorney General's (actually the Director's) decision to schedule phendimetrazine and phentermine and which could not have been relied upon by him in this decision, defendants object (1) that there are no specific findings concerning any of the eight factors prescribed for consideration by § 811(c), and (2) more generally, that the documents—"a compilation of unsynthesized raw data"—show that not all the factors could have been

relied upon in making the scheduling determinations. They argue that

> "consideration of abuse-related factors is arguable, but no more. It seems clear that only when presented with the threat of hearings, in which justification of their proposals would have to be made, did B.N.D.D. begin to carry out the responsibilities Congress delegated as necessary conditions precedent to the exercise of the delegated authority. . . .[E]xcept for documentation concerning abuse, the guiding factors upon which the Congressional delegation of authority was premised were ignored. By failing to consider all of the guidelines specified in 21 U.S.C. § 811(c), before scheduling phendimetrazine and phentermine, the Attorney General abused the authority Congress delegated to him. Therefore, the scheduling of those drugs is void, and conviction of a crime created by that scheduling would be a denial of due process."[14/]

The short answer to defendants' first objection is that the statute does not require any findings as to the factors listed in § 811(c); the statute merely requires that the Attorney General and, where applicable, the Secretary

"consider" the factors there prescribed. Where the Congress intended that the Attorney General make formal findings, it so specified, as in §§ 811(a) and 812(b), and defendants do not contend that the Attorney General failed to make those findings with respect to phendimetrazine and phentermine.[15/]

Disposition of defendants' second contention requires a more extended discussion of the chronology of the scheduling decisions and their background, as gleaned from the summarizing affidavit of defendant Pastor's counsel, the affidavit of William W. Vodra, who was Assistant Chief Counsel of the Bureau of Narcotics and Dangerous Drugs (BNDD) from 1972 to 1974, and the documentary evidence submitted by both defendants and the Government.

From 1971 to 1974, the BNDD Director made his decision to schedule a drug after receiving oral and written presentations from a committee appointed to evaluate any such proposals. On that committee were representatives of the Drug Control Division (SCID) of BNDD's Office of Scientific Support, whose function was to analyze pharmacological aspects of the drug considered for scheduling and to receive and evaluate reports of the drug's abuse that were generated by the medical community; the BNDD Office of Compliance (ENAR), which was concerned with appraisal of the diversion and illicit traffic in legitimate drugs; the BNDD

Chief Counsel's Office; along with the Chief Medical Officer of BNDD.

During 1972, the Food and Drug Administration of the Department of Health, Education and Welfare (HEW-FDA) conducted a major review of all anorectic drug products, that is, products used for weight reduction in the treatment of obesity, including phendimetrazine and phentermine. According to testimony of FDA representatives in December 1972 before the Subcommittee on Monopoly of the Senate Judiciary Committee, this study was the most comprehensive review of any class of drug products ever undertaken by HEW-FDA. At that hearing, HEW-FDA announced that it would recommend placement of most of the unscheduled prescription anorectic drugs in Schedule III of § 812.

Upon learning informally of HEW-FDA's proposal to schedule these drugs, members of BNDD's SCID unit began preliminary familiarization studies of the scientific and medical aspects of the anorectics, although, as noted previously, the findings of the Secretary as to scientific and medical matters are binding on the Attorney General. In this investigation, the SCID staff members did not have access to much of the raw data regarding drug safety that FDA was using in its study because FDA considered this information to be trade secret information which was barred from disclosure by

21 U.S.C. § 331(j). Due to the incomplete nature of their information, the SCID staff members did not attempt to forumulate a staff position on the scientific and medical aspects of these drugs. They considered the results of their study to be inconclusive, and they felt that the study results were inadequate to justify a recommendation either to control or to refrain from controlling the anorectic drugs.

On February 12, 1973, HEW-FDA published in the Federal Register a notice of its findings on the effectiveness of anorectics. Subsequently, by letter dated February 15, 1973, Richard L. Seggel, HEW Acting Assistant Secretary for Health, recommended to John E. Ingersoll, the BNDD Director, that various anorectic drugs, including phendimetrazine and phentermine, be classified as Schedule III controlled substances.[16/] Attached to the recommendation letter was some "review" material that HEW-FDA suggested might be of "possible utility" to BNDD and "a basis for further discussion".

After receiving this HEW-FDA recommendation, BNDD staff members assembled data concerning abuse of the drugs in question. These data tended to show that anorectic drugs were being used by illicit drug users to replace amphetamines, which had become more difficult to obtain since they had been placed in Schedule II. This apparent substitution

of unscheduled anorectic drugs, including phentermine and phendimetrazine, for amphetamines and phenmetrazine corroborated HEW-FDA findings about the similarity of all these drugs in chemical structure and pharmacological profile. However, the BNDD SCID staff members who had conducted the familiarization studies of these drugs were of the opinion that the Secretary's recommendation and the attached materials were insufficient to support a scheduling proposal. Thus, at a March 13, 1973 meeting of the BNDD advisory committee, it was determined that representatives of BNDD should meet personally with representatives of HEW-FDA to determine whether HEW-FDA did, in fact, have additional data which would justify scheduling the drugs.

Subsequent to the March 13 meeting, HEW-FDA supplied to BNDD some further scientific and medical documentation concerning the scheduling proposal. Then, on March 30, Drs. Robert Zendzian and Robert Potrepka from SCID and Mr. Vodra, from the Chief Counsel's office, met with the HEW-FDA officials who participated in the HEW-FDA efficacy study of the anorectic drugs proposed for control. Based on these interviews and document analyses, the BNDD representatives concluded that the witnesses and documents did provide scientific and medical information which would be sufficient to support a determination by the Director to schedule the drugs.

suggestion that such a course of inquiry would, or could,

On April 3, 1973, members of the anorectic drug scheduling committee and other BNDD staff members who had assisted in gathering and evaluating material for the decision on the HEW-FDA proposal met with BNDD Director Ingersoll to consider the possible scheduling of, inter alia, phendimetrazine and phentermine. The only documentary presentation made to the Director consisted of a memorandum of the minutes of the March 13 meeting. All other evidence was presented to the Director in oral form. These presentations included summaries of the March 30 interview with HEW-FDA officials regarding the available evidence on the pharmacological profiles and other medical and scientific aspects of the drugs; information concerning abuse of the drugs; an assessment of the impact on BNDD resources of regulating the unscheduled anorectic drugs; and a description of the parallel between the current experience with marketed, unscheduled anorectics such as phendimetrazine and phentermine, and the early appearances of amphetamine abuse in the United States.

At the conclusion of the April 3 meeting, the Director concluded that there was sufficient evidence to justify placing phendimetrazine and phentermine on Schedule III, but that he was not willing to commit considerable BNDD resources to protracted litigation over the scheduling of these drugs. Thus, Mr. Vodra was directed to meet with

manufacturers to ascertain whether they could present evidence as to why their individual drugs should not be scheduled, and whether, presumably, they would institute litigation to block the scheduling proposal.

Since only two manufacturers submitted information in response to these inquiries, the Director signed notices of proposed rulemaking for phendimetrazine, phentermine, and six other unscheduled anorectic drugs on May 1, 1973, including therein the conclusions which he had drawn from the committee's presentation,[17/] and these notices were published in the Federal Register.[18/]

When no objections to the scheduling of phendimetrazine had been received, that drug was placed in Schedule III pursuant to an order which was signed on June 12, 1973, and which incorporated the findings required by 21 U.S.C. § 812(b)(3). 38 Federal Register 15719. Since the Pennwalt Corporation, a phentermine manufacturer, had objected to the proposed scheduling of phentermine, that drug was not included in the order of June 12. Instead, preparations were begun for a hearing, pursuant to § 811(a), on Pennwalt's objections. In the interim, however, the Director secured Pennwalt's consent to placing phentermine in Schedule IV, in order that it not be abused during conduct of the hearings.

Since the statutory criteria for placing substances in Schedules III and IV are substantially the same, with the criteria for the former being a bit more stringent, and since the legal procedures for placing drugs in the two schedules are identical, the Director considered that the May 1, 1973 notice of proposed rulemaking, which had contemplated that phentermine would be placed in Schedule III, would serve as adequate notice, within the contemplation of 21 U.S.C. § 811, for placing phentermine in Schedule IV. Neither Pennwalt nor the other phentermine manufacturers who were consulted objected to placement in Schedule IV. Accordingly, the Director placed phentermine in Schedule IV in an order dated July 6, 1973 which incorporated the requisite statutory findings. 38 Federal Register 18013. Although pre-hearing procedures were conducted in late 1973 and early 1974, no hearing has yet been held on the proposal to place phentermine in Schedule III, and that drug is apparently still undergoing further evaluation by DEA.

To the procedure above outlined, and the data produced thereby, the defendants have raised a number of objections.

They object, first, that the Attorney General considered unwarranted and irrelevant matters in the course of determining whether to schedule phendimetrazine and

phentermine. In support of this contention, they point to the memorandum of the March 13 BNDD staff meeting, which revealed that the staff discussed "the possibilities of a manufacturer of a drug requesting a hearing, the chances of BNDD winning such a hearing, and the relative costs of control in the various schedules by BNDD." In addition, the memorandum revealed that expeditious handling of the Secretary's recommendation had been urged because "the manufacturers of the five(5) presently marketed drugs are aware that BNDD has received HEW's recommendation to control their drugs and any excessive delay on our part will only serve to convince them that BNDD lacks substantial evidence for their control." Moreover, according to the Vodra affidavit, at the April 3 meeting, the Director was "presented with an assessment of the impact on BNDD resources of regulating the unscheduled anorectic drugs"; which led him to direct Mr. Vodra "to meet with manufacturers to determine their response to scheduling the drugs."

The court finds this contention to be without merit. In the first place, the legislative history for one of the factors which § 811(c) directs the Attorney General to consider mandates that he consider "the economics of regulation and enforcement attendant" to a decision to schedule drugs.[19/] Thus, discussion of the probability of hearings and their anticipated costs was perfectly proper.

Secondly, the Director did not attempt to ascertain the manufacturers' response to his scheduling decision until he had already determined that there was sufficient evidence on the eight factors specified in § 811(c) to warrant placing the drugs in Schedule III. Finally, the concern to avoid an appearance of indecision in the eyes of the drug industry is not such a serious extraneous consideration as to indicate any abuse of discretion on the part of the Director. If that concern had any effect on the Director's decision, it presumably affected merely the timing of his decision, rather than its substance.

They object, second, that the evidence on which the Director allegedly relied in making his finding of the drugs' potential for abuse is inadequate in both quantity and quality, since it involves only a relatively few instances of usage and small quantities of the drugs.. they contend, the Director abused his discretion, by failing to make an adequate "consideration" of the abuse-related factors in § 811(c).

On the basis of the legislative history of the Act, however, the court finds no such abuse of discretion. The House report essentially incorporated portions of the report which had previously accompanied the Federal Food, Drug, and Cosmetic Act. In referring to the latter report, the present report noted that "[w]ith respect to the question

of the extent to which actual, as distinguished from potential abuse was required to be established, that report stated that 'the Secretary of Health, Education, and Welfare should not be required to wait until a number of lives have been destroyed or substantial problems have already arisen before designating a drug as subject to controls of the bill.'" 1970 U. S. Code Cong. and Admin. News 4602.

Thus, the fact that only relatively small quantities of the drugs may have been diverted to illicit use is by no means necessarily indicative that they did not possess any potential for abuse of which the Director should take official cognizance. It is precisely for the purpose of avoiding large scale misuse of legitimate drugs that the BNDD (and now the DEA) is staffed with people who are presumably competent to assess the significance of shifting patterns of drug usage. Thus, in addition to the quantities involved, it is significant that the evidence considered by BNDD included investigations by Texas law enforcement officials involving criminal trafficking in these drugs by physicians, reports of phentermine thefts from several wholesalers and retailers in circumstances which indicated that the purpose of the theft was criminal distribution or abuse of the drug, and non-medical use of phentermine by truck drivers. Moreover drug treatment programs also reported that phentermine had a "street name", giving some indication that it was becoming familiar among non-medical users.

On this record, the court cannot find that the Director abused his discretion in recommending that phendimetrazine and phentermine be scheduled. The instances above cited, when viewed together with the drugs' chemical similarity to to amphetamines and phenmetrazine, which had already been scheduled, clearly amount to substantial evidence from which the Director could find that these drugs possessed a potential for abuse. And the Director is not obliged to wait until misuse of these drugs has reached epidemic proportions before he takes steps to control their dispersion.

Although defendants conceded, supra, that the materials in their possession at least arguably revealed that the Director had considered the abuse-related factors of § 811(c), they vigorously assert that these materials are so deficient in data of a scientific or medical nature concerning phendimetrazine and phentermine that the Director clearly failed to consider all the factors mandated by § 811(c), and therefore abused his discretion in recommending that those drugs be scheduled as controlled substances. While this argument raises somewhat different problems than the previous contention, the court cannot find that defendants have met their burden of showing that the Director abused his discretion.

In the first place, although defendants initially requested virtually all the tangible data and reports on which the Secretary and the Attorney General relied in making their respective recommendation and decision to schedule these drugs,

they apparently received only that material which is presently in the possession of the DEA. It is not clear to the court whether defendants were specifically advised, before they made their motion, that this documentary response did not include a considerable body of scientific material which allegedly is in the possession of HEW-FDA, and which officials of that agency had not previously turned over to BNDD. However, the result of this discrepancy between request and response is that the documents which the defendants examined, and on which their motion is predicated, do not apparently contain all the medical and scientific data which the Secretary accumulated in his evaluation of these drugs.

Thus, much of defendants' carefully documented analysis of these materials loses its cogency. In the first place, as the court interprets the statute, the Attorney General need not undertake his own, independent investigation of the scientific and medical criteria and develop his own data in that regard when, as in this case, the Secretary initiates the scheduling proposal based upon his own research.[20/] The Attorney General is entitled to rely upon—and is, in fact, bound by—the Secretary's recommendations as to scientific and medical matters. Thus the adequacy of scientific and medical data independently procured by BNDD is not

determinative of the question whether the Director adequately considered the factors set forth in § 811(c).

Secondly, it appears that, in fact, the bulk of the data on which the Secretary allegedly predicated his recommendation was never turned over to the defendants in documentary form. Only a small quantity of "review" material was attached to the Secretary's letter of recommendation in February of 1973, and this material was considered by BNDD personnel to be "[in]sufficient standing alone to support a scheduling proposal." Further materials subsequently supplied to BNDD by HEW-FDA in March of 1973, and provided to defendants by DEA, include only six pages of experimental data relating to phendimetrazine and phentermine, and twelve bibliographical citations.

According to the affidavit executed by Mr. Vodra and submitted by the Government, the critical exchange of information from HEW-FDA to BNDD officials occurred orally at the meeting on March 30, 1973. It was at this meeting that the BNDD representatives were apprised of the full extent of the testimony and documents which HEW-FDA had developed in its study of the anorectic drugs. And it was this data summary which satisfied the BNDD advisory committee that it could recommend to the Director that he schedule those drugs, including phendimetrazine and phentermine, which HEW had previously recommended for control. It was then at the April 3 meeting that the

Director received the primarily oral staff presentation of research findings concerning both scientific and medical factors and also abuse-related factors. Based upon that presentation, the Director made his decision to schedule these drugs.

The Government's response to defendants' painstaking documentary analysis leaves two questions, one concerning the sufficiency of the Government's evidentiary showing and one concerning the procedures adopted by the Director in making his decision.

The Government does not attempt to parry the defendants' item-by-item analysis of the DEA documents with its own demonstration of the purportedly extensive medical and scientific data which the HEW-FDA study developed. Rather, Mr. Vodra's affidavit merely describes it in conclusory and general terms, presumably because such a demonstration of material in HEW's possession would be irrelevant to the question whether the Director abused his discretion, if he never saw the material anyway and only relied on oral summaries of its contents. Instead, Mr. Vodra simply asserts that, at the April 3 meeting, the substance of these data was conveyed to the Director, who then considered the factors which he must consider under the statute, having particular regard to the general categories of information previously mentioned by the court in the discussion of that meeting.

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is entitled to a fair and impartial trial, regardless of

The narrow question, then, is whether Mr. Vodra's sworn representation that the Secretary considered the factors required by § 811(c) at the April 3 meeting, taken together with the other material produced by the Government, constitutes a sufficient showing that the Director did not abuse his discretion in deciding to schedule these drugs. The court holds that it does, and that defendants have not sustained their burden of showing that he abused his discretion by failing to consider either the abuse-related or medical or scientific factors listed in § 811(c). Although Mr. Vodra's affidavit speaks of the April 3 meeting in rather general terms, he would presumably amplify those statements at a hearing, if the court were to order one; but the court finds his sworn statement sufficient to negate the inference of abuse of discretion.

The question of the sufficiency of the Government's affidavit is closely interrelated with defendants' challenge to the sufficiency of the procedures adopted by the Director to inform himself concerning the factors in § 811(c).

Defendants contend, first, that the meeting of March 30, of which, apparently, no transcript, memoranda, nor notes survive, was inadequate to review the medical and scientific findings of HEW-FDA. Without going so far as to explicitly suggest that the meeting was a mere fabrication of Mr. Vodra, they argue that that meeting afforded no way to

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are not to assume that I have any opinion as to the guilt

determine whether HEW-FDA, in turn, had considered all the factors which the statute requires the Secretary to consider. And, they conclude, it is strange that, after amassing almost 5000 pages of documents concerning the scheduling of these drugs, the final staff determination on five of the eight factors of § 811(c) should be left to the unrecorded determination of three individuals.

Secondly, defendants contend that the manner in which the Director reviewed the evidence amassed by his staff and that of HEW-FDA was inadequate, in that he received presentations which were almost completely oral at a meeting of which neither transcript nor memorandum survive.[21/] The decision to schedule a substance for control, they urge, should be made in a more formal manner. "When Congress delegated to the Attorney General the authority and power it did, it certainly did not mean to delegate an unbridled discretion to act. Such would be the result, however, if decisions which result in major criminal sanctions are allowed to be based upon unreviewable, oral presentations, not even effectively memorialized."[22/]

The basis on which defendants make these final contentions is not entirely clear, and the argument is not supported by authorities. The contention appears to be that these informal, oral procedures are inadequate to ensure that the Director reviews the factors which he must consider, and, therefore, that he abused his discretion in relying on them in

this case. (Correlatively, the argument must be that conviction for illicit involvement with a drug scheduled in accordance with these procedures would violate the defendants' due process rights.) Defendants do not appear to contend that Mr. Vodra's affidavit is fabricating accounts of either of the meetings or their contents.

This suggestion of procedural inadequacy finds no support in the Drug Abuse Act itself. Clearly the Congress did not see fit to explicitly require that the Attorney General or his delegee consider the factors of § 811(c) either at a hearing or in a written report. However, its failure to do so is to be contrasted with its explicit requirement, if the Attorney General initiates proceedings under § 811(b),[23] that "[t]he evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time."[24] The fact that the Congress was concerned generally with procedural propriety is manifested by its requirement that the Attorney General comply with the procedures of the Administrative Procedure Act in promulgating rules under § 811. Yet nothing in the rulemaking provisions of that legislation would require that the Director "consider" these factors at a memorialized meeting. It is sufficient for purposes of the APA that interested persons have notice of the Attorney General's proposed decision and the opportunity to express their views as to his action. There is no suggestion that such notice and opportunity for hearing were

not properly afforded by the Attorney General in this case.

The narrow question then remaining is whether, under the rubric of preventing an abuse of discretion, the court will impose further procedural requirements on the Attorney General, beyond those which the Congress has seen fit to establish in either the Administrative Procedure Act or the Drug Abuse Act itself. This the court declines to do.

Defendants' suggestion that the Director's utilization of the informal, oral procedures previously described creates an "unbridled discretion to act" because the presentations are "unreviewable" is, in the court's view, hyperbolic. His findings and recommendations to schedule drugs as controlled substances are subject to public scrutiny through the notice and hearing provisions of the Administrative Procedure Act, and are subject to judicial review pursuant to 21 U. S. C. § 877. Although Congress has not required that he make written findings as to the factors he must consider in § 811(c), any allegation that he failed to make the requisite consideration can be tested—and his discretion reviewed—in precisely the manner in which it is being tested in this case, by procuring the sworn testimony of those individuals who participated in the process, and, if necessary, obtaining further documentation. Any conceivable

suggestion that such a course of inquiry would, or could, be frustated by a systematic pattern of perjury would be irresponsible and clearly finds no support in this record. Absent any more convincing demonstration of the inaccuracy or inadequacy of this mode of review, the court is unwilling to impose further procedures and paperwork on an internal agency function.

The motion to dismiss the indictment is, accordingly, denied.

Dated: New York, New York
May 26, 1976

/s/ CONSTANCE BAKER MOTLEY

CONSTANCE BAKER MOTLEY
U. S. D. J.

FOOTNOTES

1. Phendimetrazine is listed as a Schedule III drug, while phentermine is listed as a Schedule IV drug.

2. This section has since been repealed. Pub. L. 91-513, Title II, § 701(a), Oct. 27, 1970, 84 Stat. 1281.

3. Sec. 811(c): "In making any finding under subsection (a) of this section or under subsection (b) of section 812 of this title, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

(1) Its actual or relative potential for abuse.
(2) Scientific evidence of its pharmacological effect, if known.
(3) The state of current scientific knowledge regarding the drug or other substance.
(4) Its history and current pattern of abuse.
(5) The scope, duration, and significance of abuse.
(6) What, if any, risk there is to the public health.
(7) Its psychic or physiological dependence liability.
(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter."

4. The fact that the Attorney General may refuse to schedule a substance in the face of the Secretary's recommendation that he do so merely reduces, rather than increases, the danger of an arbitrary reclassification with attendant criminal penalties.

FOOTNOTES

5. See note 3, supra.

6. They also cite the following portion of an internal HEW memorandum, authored by Dr. Henry E. Simmons and obtained by defendants as part of their pre-trial discovery, as proof that the criteria set forth in the statute are of little or no value in guiding administrative decisions: "These eight factors [found in § 811(c)] unfortunately are for the most part vague and redundant. The list exhibits circular reasoning and lack of parallelism, particularly when viewed together with the definitions of the schedules. Most importantly, the list of factors and the definitions of the schedules leave undefined the concepts of drug abuse potential, of drug dependence, and of risk to public health. In short, the factors provide little practical guidance in deciding particular cases."

Since Dr. Simmons worked for HEW, rather than the Justice Department, to which the Act had entrusted the primary responsibility for evaluating the "potential for abuse" factor, it is not surprising that he was unfamiliar with the standards applied by the latter department in evaluating that factor.

7. The Secretary must consider the scientific or medical aspects of a drug's potential for abuse. § 811(b).

8. Sections 811(a) and 812(b).

FOOTNOTES

9. See 1970 U. S. Code Cong. and Admin. News, pp. 4601-2.

10. H. R. Rep. No. 91-1444, Sept. 10, 1970, quoted in 1970 U. S. Code Cong. and Admin. News, pp. 4601-2.

11. See the citations collected by the First Circuit Court of Appeals in White, supra, at 9.

12. See note 3, supra. Section 811(b) also speaks in mandatory terms regarding the Secretary's consideration of scientific and medical factors.

13. The Drug Enforcement Administration is the successor agency to the Bureau of Narcotics.

14. Defendants' Memorandum in Support of Omnibus Motion, pp. 45-6.

15. The findings concerning phendimetrazine were published in 38 Federal Register 15721 (June 15, 1973) and the findings concerning phentermine were published in 38 Federal Register 18013 (July 6, 1973).

16. By virtue of 21 U.S.C. § 811(f), the Secretary must notify the Attorney General if certain new drugs have a potential for abuse.

FOOTNOTES, cont'd

17. The Director's conclusions as to the phendimetrazine were as follows:

"(1) Phendimetrazine is chemically similar to and related to the other anorectic drugs being proposed for control, and to the amphetamine, methamphetamine, and phenmetrazine substances currently listed in Schedule II.

"(2) Phendimetrazine has a pharmacological profile which is similar to the other anorectic drugs being proposed for control and to amphetamine, methamphetamine, and phenmetrazine. This general similarity suggests that all of these drugs may be reasonably substituted for each other for therapeutic or abuse purposes.

"(3) Phendimetrazine is covered by a new drug application approved by the Food and Drug Administration for use in treatment of obesity.

"(4) Products containing benzphetamine, chlorphentermine, diethylpropion, phendimetrazine, or phentermine have been marketed in the United States for several years. In the last 6 months, certain of these products have been reported as the subject of thefts, diversion, illicit sales, and abuse. Quantitatively, this data does not suggest a widespread problem at the present time; qualitatively, the data indicates a trend to methamphtetamine in abuse circles. This reinforces the belief that abuse of the pharmacologically similar drugs will increase as the amphetamines and methamphetamine become less and less available.

"(5) The legislative history of the Controlled Substances Act makes clear that the

FOOTNOTES, cont'd

Bureau is to schedule drugs based upon their potential for abuse, and 'should not be required to wait until a number of lives have been destroyed or substantial problems have arisen before designating a drug as subject to controls.'"

The Director further concludes that:

". . .control of all anorectic drugs is desirable at this time to insure that they will not become widely abused. This scheduling will fulfill the Congressional mandate to act before substantial problems have arisen."

The phentermine notice was virtually identical to that for phendimetrazine.

18. The phentermine notice was published on May 9, 1973. The papers do not reveal when the phendimetrazine notice was published.

19. "(4) The scope, duration, and significance of abuse. - In evaluating existing abuse, not only must the Attorney General know the pattern of abuse, but he must know whether the abuse is widespread. He must also know whether it is a passing fad, or whether it is a significant chronic abuse problem like heroin addiction. In reaching his decision, the Attorney General should consider the economics of regulation and enforcement attendant to such a decision. In addition, he should be aware of the social significance and impact of such a decision upon those people, especially the young, that would be affected by it." 1970 U. S. Code Cong. and Admin. News, p. 4603. (Emphasis added)

FOOTNOTES, cont'd

20. The court has noted that § 811(b), in requiring the Attorney General to request an evaluation of scientific and medical matters from the Secretary, does provide that he do so "after gathering the necessary data". However, the court construes that latter phrase to be inapplicable to cases, such as this, where the Secretary himself requests that substances be scheduled based upon research which he has already completed.

21. Neither a transcript nor a memorandum of the minutes of the meeting was ever prepared. The only extant memorandum is that presented to the Director before the meeting.

22. Defendants' Reply Affidavit in Support of Motion, pp. 6-7.

23. As he did not in this case. The Secretary initiated the Attorney General's action pursuant to § 811(f).

24. Defendants do not suggest that this phrase in the statute invalidates the procedure which the Director utilized at the March 30 meeting.

THE COURT: Please bring in the jury.

Gentlemen, I don't want any talking at all during the charge by anybody; is that clear?

(Jury present.)

THE COURT: Ladies and gentlemen, first of all I want to thank you for your patience. I know that there have been times when you have had to sit in the jury room while I discussed legal problems with the lawyers out of your presence and those occasions have sometimes been lengthy, but as I told you when the trial commenced, such discussions are necessary and they inevitably occur during the course of any criminal trial, but that patience is an important virtue in insuring that justice is done in any case.

I want to thank you for the careful attention also that you have paid to the testimony and other evidence as it has come in. I know that in order to serve on this jury each of you has had to make some personal or business sacrifice in order to be here, but you may recall when the trial commenced, I believe I told you then that we all have a stake in the fair and impartial administration of justice and that trial by jury is a basic and cherished institution in our system and that consequently when you serve on a jury you are playing a

vital role in the administration of justice. So that I am sure that any business or personal sacrifice which you had to make in order to serve on this jury, you were glad to do so in the interest of the fair and impartial administration of justice.

Before formally beginning the charge, I would also like to thank the lawyers on both sides of this case for their patience and cooperation with the Court and to congratulate each of them on the high degree of professional skill which each has demonstrated thoughout the trial.

I trust that you will bear with me, ladies and gentlemen, and give me that same degree of attention which you have given to the testimony and other evidence in the case so that you may carefully understand the legal principles which you are to apply to the facts in this case as you find them.

As you approach the performance of your function in this case, that is the determination of the guilt or innocence of each defendant, please remember that it is your duty to weigh the evidence calmly and dispassionately, without sympathy or prejudice for or against either the Government or either of the defendants. You must bear in mind that every defendant appearing before this Court

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is entitled to a fair and impartial trial, regardless of his occupation or station in life.

The fact that the Government is a party here and that the prosecution is brought in the name of the United States of America entitles it to no greater consideration than that accorded to any other party to a litigation. By the same token it is entitled to no less consideration and that is because in our system of justice all parties stand equal before the law, that is, the Government and individuals alike.

My function is simply to instruct you as to the law applicable to this case. As I pointed out, it is the jury's function, not the Court's function, to determine whether the defendants are guilty or not guilty. My function simply is to instruct you as to the law and you should accept the law as I state it to you in these instructions and apply it to the facts as you find them.

The logical result of that application is a verdict in the case which must be returned separately as to each defendant and separately as to each count.

I want to caution you that you are not to single out any one instruction alone as stating the law, but you must consider these instructions as a whole. You

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are not to assume that I have any opinion as to the guilt or innocence of a defendant or the truth or falsity of any of the charges.

The fact that I have denied motions or granted motions in the course of the trial is not to be taken by you as an indication that the Court believes the defendants are either guilty or not guilty. These motions, as I told you earlier when the trial began, are matters of law and my rulings on these motions are matters of law and have nothing to do with the province of the jury, which is to determine the guilt or innocence of the defendants.

If during the course of the trial a question was asked and an objection interposed, and I sustained the objection, you are to disregard the question and alleged facts contained in that question. Similarly, if I ruled that an answer be stricken, you are to disregard both the question and the answer in your deliberations.

During the course of these instructions I may refer to some of the testimony or some of the exhibits or some of the facts in the case. That does not mean that I think that that is the most important evidence or the only evidence. In deciding the guilt or innocence of these defendants as to each count separately you must

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consider all of the evidence in the case, all of the testimony, both direct and cross-examination, and all of the exhibits as well as any stipulations that the parties may have entered into.

You are the sole and exclusive judges of the facts in this case, which means that you pass upon the weight of the evidence, you determine the credibility, the believability of the witnesses who testified here before you, and in doing so you resolve such conflicts as there may be in the testimony or in the evidence, and you are entitled to draw such reasonable inferences as may be warranted by the testimony and other evidence in the case. That, as I have indicated, is the jury's function, and in that connection I remind you again that with respect to any fact matter it is your recollection of what the testimony or other evidence shows and not the lawyers' nor my recollection. Anything that counsel for the Government may have said or counsel for the defendants may have said with respect to any matter in evidence, or anything which I may have said or may now say is not to be substituted by you for your own recollection of what the facts and the evidence show.

There are six counts in the indictment and your verdict as to each count must be based solely on the evi-

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dence presented in this case, and, as I told you repeatedly earlier, the evidence in a case consists of three things:

The testimony which you heard from the witnesses, the exhibits which were actually received into evidence, and any stipulations as to certain facts which the lawyers entered into.

Your verdict as to each count, of course, must be unanimous and is either guilty or not guilty, and I repeat, your verdict as to each count must be based solely on the evidence in the case.

Again, in determining the guilt of a defendant you must bear in mind that guilt is personal, and that is to say that the guilt or innocence of a defendant must be determined separately with respect to him, solely on the evidence presented against him or the lack of evidence.

Now we come to the issue of credibility which I mentioned a few moments ago, which is your function as jurors in this case, and that is to determine the credibility, the believability of the witnesses who have testified. You know, of course, there is no automatic way to determine who is telling the truth and who is not. Credibility can be equated with believability and reliability. If a witness is credible you say he is believable

and reliable. If he is incredible you say he is unbelievable. In other words, there is nothing mysterious about these words.

Now, by what yardstick are you to judge the credibility or believability of the witnesses? Each of you has given careful consideration or careful attention to the testimony as it came from the witnesses themselves. You observed the witnesses. Issues of fact are presented for your determination. An issue of fact is presented, for example, if one witness testified that a certain thing occurred and another witness testified that it did not occur. In this case, as in every case, the resolution of any conflicting testimony depends upon the credibility which the jurors attribute to the testimony of various witnesses and the support or lack of support that that testimony received from other evidence in the case. Your duty is to decide the disputed issues of fact. In doing so, use your logic, your reason and your common sense. Do not be sidetracked or diverted or distracted by what you consider to be a minor or insignificant detail or irrelevancy, or by what you consider to be an appeal not to your reason or logic, but to mere sentimentality or unthinking passion. I repeat, use your common sense. You should carefully scrutinize all the

testimony given, both direct and cross-examination, the circumstances under which each witness has testified and every matter in evidence which tends to show whether a witness is worthy of belief. Consider each witness' intelligence, motive and state of mind and demeanor and manner while testifying here on the witness stand. Consider each witness' ability to observe the matters as to which he has testified and whether he impresses you as having an accurate recollection of these matters.

Consider also any relationship each witness may bear to either side of the case and the extent to which, if at all, each witness is either supported or contradicted by other evidence in the case.

Inconsistencies or discrepancies in the testimony of a witness or between the testimony of different witnesses may or may not cause the jury to discredit such testimony. Two or more persons witnessing an incident or a transaction may see or hear it differently and innocent misrecollection like failure of recollection is not an uncommon experience. In weighing the effect of a discrepancy always consider whether it pertains to a matter of importance or an unimportant detail and whether the discrepancy results from innocent error or intentional falsehood.

full meaning of the word is commonly understood only

In determining credibility and the weight to be given to the testimony of any witness you must also consider the testimony of the Government witnesses. The mere fact that they are employees of the Government entitles them to no more and no less consideration than any other witness. Nor should you be influenced by the number of witnesses called or the number of documents received in evidence. It is the quality of the testimony and other evidence which counts, not the quantity.

Now, after making your own judgment you will give the testimony of each witness such credibility, if any, as you think it deserves. If you find that any witness has wilfully testified falsely to any material matter you may reject the entire testimony of that witness or you may accept such part or portion as commends itself to your belief or which you find corroborated by the evidence in the case.

Now, during the course of the trial you heard the testimony of Charles Fernald and Douglas Berry, persons who testified concerning their involvement in the crimes charged in the indictment, and they are in fact named in Count 1 as co-conspirators but not as defendants. These persons are called accomplices. Under the law in order for one to be an accomplice he must have been involved in

the commission of the crime or crimes with which a defendant is charged. He must be a participant in that crime or crimes. An accomplice does not become incompetent as a witness because of his participation in the criminal act charged. His testimony is not to be rejected unless the jury thinks it has no weight. Like any other testimony, it is to be considered and dealt with by the 12 men and women who are the triers of fact. Such evidence is properly considered with care and scrutiny, checked up with the other facts in the case and given appropriate weight.

The testimony of an accomplice alone, if believed by you, may be of sufficient weight to sustain a verdict of guilty, even though it is not corroborated or supported by other evidence in the case. But, again, you should keep in mind that the testimony of an accomplice is always to be received with caution and weighed with great care. You are instructed that in weighing the testimony of Government witnesses charged as co-conspirators in the indictment, you may take into account any motive which you find the witness may have in testifying for the Government.

The fact that a witness may have a motive for testifying for the Government does not disqualify that

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witness, but such motive may well affect the weight you give the testimony of such a witness in adjudging the guilt or innocence of these defendants.

(Continued on next page.)

jury and before the trial commenced, an indictment is

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There was evidence also that some of these witnesses who testified, at least -- I guess Fernald and Douglas both have been convicted of a crime in the past. At least one of them anyway that I recall.

Evidence that a witness has been convicted in the past of certain crimes may also be considered by you in assessing his credibility.

This is not to say that a person with a prior record is to be deemed incapable of telling the truth. Prior convictions may, however, as I said, be considered when you are determining the believability of such a witness.

There has also been evidence of prior inconsistent statements during the course of the trial made by certain witnesses. A prior inconsistent statement is a statement allegedly made by a witness at some point prior to his testimony in court which is inconsistent or contradictory to all or part of that witness' testimony in court.

If you find that a witness made a prior inconsistent statement, you may also consider that fact for its effect upon the witness' credibility.

In other words, you may consider whether or not you believe the witness, or accept his testimony in

light of the fact that he made a prior inconsistent statement, if you so find.

One element of the government's proof in this case is the identification of the defendant Edward Pastor by the witness Edward Gallagher, an employee of the APA Transport Company.

Mr. Gallagher in his testimony identified Mr. Pastor as the person who on two occasions represented himself as Dr. Johnson and picked up packages addressed to Dr. Johnson.

The defense questions the accuracy of that identification and contends that it resulted from a suggestive photo showup that Mr. Gallagher subsequently viewed and which was shown to him by government agents.

I charge you that eyewitness identifications are to be scrutinized with great care. You recall that Mr. Pastor's only alleged contact with Mr. Gallagher were two meetings of two or three minutes duration.

In judging Mr. Gallagher's subsequent identification of Mr. Pastor, you should evaluate the circumstances of such meetings and Mr. Gallagher's opportunity and capacity to observe the person being identified during such meetings.

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You may also consider the circumstances under which the subsequent identification was made.

If the identification by the witness may have been influenced in your judgment by the circumstances under which the defendant's picture was presented to him for identification, you should scrutinize the identification with great care.

You may also consider the length of time that elapsed between the confrontation and the next opportunity of the witness to see the defendant as a factor bearing on the reliability of the identification.

Finally, you must consider the credibility of the identification witness in the same way as any other witness, as I have just charged you on credibility.

You will recall that we also had an expert witness in this case, the handwriting expert. And so I want to say a word about expert testimony.

The expert gave qualifications in his field and in a case involving a matter of science or art, or some field requiring special knowledge or skill not ordinarily possessed by the average person, an expert is permitted to state his opinion for the information of the Court and jury.

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The opinions stated by an expert are based upon particular facts as the expert himself observed them and testified as to those facts, or based upon facts which the attorney who questioned him asked him to assume for the express purpose of stating an opinion.

You may reject an expert's opinion if you find the facts to be different from those which form the basis for his opinion.

You may also reject his opinion, if, after careful consideration of all the evidence in the case, expert and other, you disagree with the opinion.

In other words, you are not required to accept an expert's opinion to the exclusion of the other facts and circumstances disclosed in the record and the other testimony.

Such an opinion is subject to the same rules concerning reliability and credibility as the testimony of any other witness. It is given to assist you in reaching a proper conclusion. It is entitled to such weight as you find the expert's qualifications warrant and must be considered by you, but is not controlling upon your judgment.

As you know, neither defendant has taken the witness stand in this case. The fact that a defendant,

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who has a right to do so, has not taken the stand and testified in this case does not create any presumption against him and cannot be considered by you as any evidence against him, or a basis for any inference unfavorable to him. You must not permit such fact to weigh in the slightest degree against the defendant, nor should it enter into your discussions or deliberations.

As I stated before, the law never imposes upon a defendant in a criminal case the burden or the duty of calling any witnesses or producing any evidence.

The witness Agent Vigna has testified that Mr. Pastor made incriminating statements to him during interrogations at the Drug Enforcement Administration offices here in New York.

In other words, you have heard evidence upon the issue of the voluntariness of those alleged statements as a result of examination and cross-examination, including Mr. Pastor's state of health at the time, the medication he was taking, his impending hospitalization and various statements by Agent Vigna made at the time, such as the one in which he indicated thathe didn't want to hear denials from Mr. Pastor.

You may consider this evidence as to the voluntariness of the statements allegedly made to Agent

Vigna which have been admitted into evidence and then give those statements such weight, if any, as you believe they deserve under the circumstances.

Of course, you also must assess the credibility of Agent Vigna, as you must do any other witness, and reach a determination whether or not such statements were ever made by Mr.Pastor, or whether they were made in a much altered form differing in substance and content than that testified to.

It is only if you find that the statements were made that you are to consider their voluntariness and thus the weight to be accorded them.

Furthermore, I charge you that a confession made outside of court by one defendant, such as those alleged to have been made by defendant Pastor, may not be considered against another defendant not a party to such confession such as the defendant Weiner in the present instance.

As I told you there are six counts or charges in the indictment. As you well know, the reason you are here is that each defendant has entered a plea ofnot guilty to each charge made against him in the indictment.

As I told you when the trial commenced,

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if a defendant is to be found guilty of any charge it must be as a result of your conviction the government has sustained its burden of proof, and that is to prove the defendant guilty of a particular charge beyond a reasonable doubt.

That is a burden which never shifts in a criminal case. It remains upon the government throughout the entire trial.

A defendant does not have to prove his innocence. On the contrary, as I told you when the trial commenced, a defendant is presumed to be innocent of any charge made against him in an indictment.

This presumption of innocence was in the defendants' favor when the trial commenced, continued in their favor throughout the trial. This presumption of innocence is in their favor even as I instruct you now.

The presumption of innocence remains in their favor during the course of your deliberation in the jury room. This presumption of innocence is removed only if and when, after your deliberations in the jury room, you come to the conclusion that the government has sustained its burden of proof which is to prove the defendant guilty of a particular charge beyond a reasonable doubt.

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The question that naturally comes up is, what is a reasonable doubt? The words almost define themselves.

A reasonable doubt is a doubt founded in reason and arising out of the evidence in the case or the lack of evidence. It is a doubt which a reasonable person has after carefully weighing all the evidence, the kind of doubt which would make one hesitate to act.

It means a doubt that is substantial, not merely shadowy.

A reasonable doubt is one which appeals to your reason, your judgment, your common sense and your experiences in life. It is not caprice, whim, or speculation. It is not an excuse to avoid the performance of an unpleasant duty. It is not sympathy for a defendant.

If after a fair and impartial consideration of all the evidence you can candidly and honestly say that you are not satisfied of the guilt of a particular defendant that you are then considering and that you do not have an abiding conviction as to that defendant's guilt, such a conviction as you would be willing to act upon unhesitatingly in important and weighty matters in the personal affairs of your own life, then

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you have a reasonable doubt and in that circumstance it is your duty to acquit the defendant.

On the other hand, if after such a fair and impartial consideration of all the evidence you can candidly and honestly say that you are satisfied of the guilt of the defendant, that you do have an abiding conviction as tothe defendant's guilt, such a conviction as you would be willing to act upon unhesitatingly in important and weighty matters in the personal affairs of your own life, then you have no reasonable doubt and in that circumstance you may convict the defendant.

A reasonable doubt does not mean a positive certainty or beyond all possible doubt. That is because it is practically impossible for a person to be absolutely and completely convinced of any controverted fact which by its nature is not susceptible to mathematical certainty.

In consequence, the law in a criminal case is that it is sufficient if the guilt of a defendant is established beyond a reasonable doubt, not beyond all possible doubt.

What you must remember is that you may not vote to convict based on suspicion or conjecture or speculation no matter how strong. A conviction can

only be based on actual proof of guilt beyond a reasonable doubt, and if the proof does not meet that standard, you must acquit.

There are two classes of evidence recognized and admitted in courts of justice upon either of which you may find an accused guilty of a crime. One is called direct evidence. The other is called circumstantial evidence.

Direct evicence tends to show the fact in issue without need for any other amplification, although, of course, there is always a question whether that evidence is to be believed.

Circumstantial evidence, on the other hand, tends to show other facts from which the fact in dispute may reasonably be inferred.

It is that evidence which tends to prove the fact in issue by proof of other facts which have a legitimate tendency to lead the mind to infer that the facts sought to be established are true. In other words, circumstantial evidence concerns facts proved from which the jury may infer by a process of reasoning other facts in dispute.

It is not necessary that the participation of a defendant be shown by direct evidence. The defend-

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ants connection to a crime charged may be inferred from such facts and circumstances in evidence as would legitimately tend to sustain such an inference.

Knowledge and wilfulness and intent of a defendant need not be proved by direct evidence. Like any other fact in dispute it may be established by circumstantial evidence.

In every criminal case it is necessary for the government to prove beyond a reasonable doubt the defendant on trial has the necessary criminal knowledge, wilfulness and intent. Questions concerning a defendant's knowledge and wilfulness and intent involve proof of a defendant's state of mind at the time of the alleged crime.

It is obviously impossible to prove directly the operation of a person's mind because you can not look into a person's mind and see what his or her intentions are or were, but the proof of the circumstances surrounding a defendant's activities may well supply an adequate and convincing basis for finding that the defendant acted knowingly, wilfully and intentionally.

In other words, the actions of a defendant must be judged in their time and place just as the

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full meaning of the word is commonly understood only in its relation to other words in a sentence or in its context.

So the meaning of a particular act or conduct on the part of a defendant may depend upon the circumstances surrounding that act or conduct.

In determining the issue of knowledge, wilfulness and intent you are entitled to consider any statements made by the defendant which are in evidence and any acts done by the accused which are in evidence and all facts and circumstances in evidence which may aid you in determining the defendant's state of mind.

You may consider such things as the age, background, occupation and experience of a defendant and whether such facts make it likely or unlikely, probable or improbable, that a defendant fully and precisely understood what he was doing in regard to a transaction, and, where relevant, in relation to others.

The government has pointed to evidence, or offered evidence during the trial which it claims shows an act by a defendant on trial here similar to the ones charged in the indictment. And I instructed you specifically at the time regarding that evidence. I want to say another word about it at this time.

The defendant is not on trial for that event relating to that alleged similar act. You may, however, consider in determining whether defendant acted with guilty knowledge or unlawful intent on the charges before you the fact, if you find it true, that he engaged in another transaction similar to that charged in the indictment. And that evidence related to the defendant Weiner.

As I have said, you may consider such evidence only on the question of knowledge, wilfulness and intent of the defendant Weiner.

During the trial there have been admitted into evidence certain exhibits which we have referred to as charts or schedules or summaries. This exhibit is not, as I told you, at least when it was offered, independent proof.

The exhibit purports to be only a visual representation or resume of information or data set forth in exhibits received in evidence, or the testimony of a witness.

If the information contained in the exhibits or in the testimony is converted into a visual or pictorial form and the chart or summary is marked as an exhibit, the chart or the summary does not have an

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independent value as proof because it is only based upon the testimony and the exhibits in evidence. It is a visual aid, I said, just something to help you understand what it is in the exhibit or the testimony.

So you understand that the chart or schedule which is in evidence is not, as I said, independent proof. The evidence in this case, as I said, is the testimony, the exhibits actually received in evidence and the stipulations of counsel.

The charts are no better or the schedule is no better than the evidence and the testimony on which it is based.

It is for you to decide whether the chart correctly presents the data or the evidence in the record.

With this instruction in mind, you are entitled to consider the chart received in evidence, if you find that it assists you in some way in analyzing the evidence and understanding the evidence.

Remember that it is your recollection of the evidence which governs and not what is said on the chart.

Now we come to the indictment itself. As I told you when you were being selected to sit on this

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jury and before the trial commenced, an indictment is not proof or evidence. It merely contains a series of accusations and it is a method or technique which we employ in system whereby persons who are accused by a grand jury of crimes are brought into court and then their guilt or innocence is determined by a petit jury, or a trial jury such as you are.

Therefore, the indictment has no evidentiary value and should not be considered by you as proving or tending to prove any of the crimes charged in it.

The government, as I told you, has the burden of proving each charge beyond a reasonable doubt. And what I am going to do now is to read each charge to you and then I am going to tell you what the essential elements of each charge are, which you must find the government has established beyond a reasonable doubt before you may find a defendant guilty of that particular charge.

By entering a plea of not guilty to each charge the defendant has put in issue the essential elements of each crime charged. And, as I told you, the government has the burden of proving each of those essential elements of each crime charged before a defendant may be convicted of that count.

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If the government fails to prove one element then the defendant must be acquited of that particular charge.

During the course of the indictment, reading the indictment, you will hear these words: "Unlawfully, wilfully and knowingly."

So I want to explain now what is meant by those terms.

Unlawfully obviously means contrary to law.

An act is done knowingly if it is done voluntarily and purposely and not because of mistake, accident, mere negligence or other innocent reason.

The act is done wilfully if it is done knowingly deliberately, intentionally and with an evil motive or purpose.

As I told you before, knowledge and wilfulness and intent of a defendant need not be proved by direct evidence. Like any other fact in issue it may be established by circumstantial evidence.

The indictment in this case charges in essence that the two defendants Edward Pastor and Martin Weiner illegally obtained phendimetrazine and phentermine which are respectively schedule 3 and 4 controlled drugs under federal law and that they conspired with each other

and other persons so to do.

Count 1, which is the conspiracy charge, charges that the two defendants conspired to obtain these controlled drugs by misrepresentation and forgery, including use of a registration number which had been issued to another person and which was in fact suspended.

Count 1 charges that another objective of the conspiracy was for the defendant to acquire and obtain possession of schedule 3 and 4 controlled substances by misrepresentation, fraud, forgery, deception and subterfuge.

Count 1 further charges that it was an objective of the conspiracy that the defendants unlawfully, intentionally and knowingly would distribute and possess with intent to distribute schedule 3 and 4 controlled substances.

Counts 2 through 6 charge that on five specific occasions the defendants obtained phendimetrazine and phentermine by misrepresentation and fraud.

Now I am going to read to you count 1 of the indictment which is the conspiracy count.

"The grand jury charges, paragraph 1, from on or about the first day of March, 1973, and continuously thereafter up to and including the date of the filing

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of this indictment in the Southern District of New York and elsewhere Edward Pastor and Martin Weiner, the defendants, Charles Fernald and Douglas Berry, named herein as co-conspirators, but not as defendants, and others to the grand jury unknown, unlawfully, intentionally and knowingly combined, conspired, confederated and agreed together and with each other to violate section 812, 841A1, 843A2 and 843A3 of title 21, United States Code.

"Paragraph 2. It was part of said conspiracy that said defendants unlawfully, intentionally and knowingly would, in the course of the distribution of schedule 3 and 4 controlled substances, use a registration number which was suspended and issued to another person in violation of sections 812, 843A2 of title 21, United States Code.

"Paragraph 3. It was further part of said conspiracy that the said defendants unlawfully, intentionally and knowingly would by misrepresentation, fraud, forgery, deception and subterfuge acquire and obtain possession of schedule 2, 3 and 4 controlled substances in violation of sections 812, 843A3 of title 21. United States Code.

"Paragraph 4. It was further part of said conspiracy that the said defendants unlawfully,

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intentionally and knowingly would distribute and possess with intent to distribute schedule 3 and 4 controlled substances, the exact amounts thereof being to the grand jury unknown, in violation of sections 812 and 841A1 of title 21, United States Code.

"Paragraph 5. Among the means by which the defendants and their co-conspirators would and did carry out the conspiracy were the following:

"The defendants Edward Pastor and Martin Weiner did order and receive from co-conspirator Charles Fernald, a broker engaged in the business of distributing drugs, phendimetrazine and phentermine which are respectively schedule 3 and schedule 4 controlled substances under federal law.

"The defendants Edward Pastor and Martin Weiner were not registered with the Federal Drug Enforcement Administration or its predecessor to purchase phendimetrazine and phentermine, although, as these defendants well knew, only persons so registered could legally purchase phendimetrazine and phentermine.

"That in an attempt to evade this requirement of the law, the defendants Pastor and Weiner falsely represented to co-conspirator, Charles Fernald, and others that they were ordering the phendimetrazine and phentermine

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for a Dr. Horace Johnson, who they falsely represented was a physician registered with the Drug Enforcement Administration and its predecessor to receive phendimetrazine and phentermine.

"Through the use of forged documents and other fraudulent means the defendants Edward Pastor and Martin Weiner did order and receive more than 5 million phendimetrazine and phentermine tablets and capsules.

"In pursuance of said conspiracy, and to effect the objects thereof, the following overt acts were committed in the Southern District of New York and elsewhere:

"1. In or about May 1973 Edward Pastor, the defendant, told Charles Fernald that when Pastor ordered drugs Pastor did not want invoices sent to Pastor or Dr. Horace Johnson.

"2. On or about June 22, 1973, Martin Weiner, the defendant, paid Charles Fernald $4,475 in cash and received 800,000 phendimetrazine tablets in Manhattan, New York.

"3. In or about June, 1973, Martin Weiner, the defendant, told Charles Fernald over the telephone that the 800,000 phendimetrazine tablets that Weiner had ordered from Fernald were intended for a doctor.

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"4. In or about September, 1973, Edward Pastor, the defendant, told Charles Fernald that the 250,000 phendimetrazine capsules that Pastor was ordering were intended for Dr. Horace Johnson.

"5. In or about October, 1973 Edward Pastor, the defendant, ordered one million phendimetrazine capsules from Dr. Horace Johnson.

"6. On or about November 23, 1973, Edward Pastor, the defendant, caused the signature of Dr. Horace Johnson to be forged on a letter that purported to be a confirmation of an order for phendimetrazine capsules.

"7. In or about 1974 at the APA Transport Terminal in Philadelphia, Pennsylvania, Edward Pastor, the defendant, falsely stated to an employee of APA Transport that Pastor was Dr. Horace Johnson.

"8. In or about April, 1974, Edward Pastor, the defendant, ordered one million phentermine tablets for Dr. Horace Johnson from Charles Fernald.

"9. In or about April 18, 1974, Edward Pastor, the defendant, caused the signature of Dr. Horace Johnson to be forged on a letter that purported to be an order by Dr. Horace Johnson for one million phentermine tablets."

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Now, what is a conspiracy? A conspiracy may be defined as a combination of two or more persons to accomplish an unlawful purpose by concerted action -- in this case to illegally obtain and distribute the controlled drug substances phendimetrazine and phentermine. A conspiracy to commit a crime is an entirely separate and distinct offense from the substantive crime that the conspiracy was formed to accomplish. Thus, in a conspiracy charge there is no need to prove an actual violation of the substantive law, that is, that a defendant did illegally obtain or distribute controlled drug substances. If there was an agreement between one or more persons to illegally obtain and distribute controlled drug substances, and a defendant was one of the persons agreeing or who later joined the agreement, and one or more acts were done to bring about the objective of that agreement, the conspiracy statute is violated. Thus, if a conspiracy existed, even if it should fail in its purpose, it is still punishable as a crime.

Now, the indictment cites Title 21, United States Code, Section 846 as the statute violated in Count 1, and that statute provides in pertinent part as follows:

"Any person who attempts or conspires to commit any offense defined in this subchapter is

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guilty of a crime."

Of course, the chapter has to do with the regulation and control of these drugs.

Now, in order to prove the crime of conspiracy against each defendant in this case, the Government must have proved to your satisfaction beyond a reasonable doubt the following essential elements of the crime of conspiracy:

First, that some time on or about the period between March 1, 1973 and March 12, the date of the filing of the indictment, an agreement existed between two or more persons.

Second, that it was an object of this agreement to either (1) obtain controlled substances by use of a registration number which was issued to another person or suspended; or (2) to obtain controlled substances by misrepresentation, fraud, forgery, deception, or subterfuge; or (3) to distribute or possess with intent to distribute controlled substances.

Now, the third element is that the defendant knowingly and wilfully associated himself with the conspiracy, that is, became a member of it.

The fourth element is that at least one of the conspirators committed at least one of the overt acts

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charged in the indictment at or about the time and place alleged here in the Southern District of New York.

Thus, in essence, the conspiracy charged is proven when a criminal agreement is proven and it is shown that the defendant became a member of the conspiracy with knowledge of its purposes, and when it is established that someone performed at least one overt act in furtherance of the conspiracy.

Now I want to discuss each of these elements in greater detail. The first element, the existence of the conspiracy:

To establish that a conspiracy existed, the Government is not required to show that two or more persons such as the conspirators named in this indictment sat around a table and entered into a solemn compact orally or in writing stating that they have formed a conspiracy to violate the law, setting forth details of the plan, the means by which the unlawful project is to be carried out or the part to be played by each conspirator. Indeed, it would be extraordinary if there were such a formal document or specific oral agreement. Your common sense will tell you that when individuals in fact undertake to enter into a criminal conspiracy much is left to unexpressed understanding. Conspirators do not usually

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reduce their agreements to writing or acknowledge them before a notary public, nor do they publicly broadcast their plans. From its very nature a conspiracy is almost invariably secret and is characterized by secrecy rendering detection more difficult.

Therefore, if you find from the evidence that two or more persons in any manner, through any contrivance, impliedly or tacitly, came to a common understanding to violate the law, that would be sufficient. Express language or specific words are not required, as I said, to indicate assent or attachment to a conspiracy.

In determining whether there has been an unlawful agreement you should consider acts and conduct of the alleged co-conspirators which are done to carry out an apparent criminal purpose. The old adage "Actions speak louder than words" is applicable here. And in this connection, proof concerning the accomplishment of the objective of the conspiracy may be the most persuasive evidence of the existence of the conspiracy itself.

Now, as to the second element, unlawful purposes of the conspiracy, the indictment charges that the unlawful purposes of the conspiracy in this case were, one, to obtain controlled drug substances by use of a registration number which was issued to another person

or suspended, in violation of Section 843(a)(2) of Title 21, United States Code.

That statute provides in pertinent part as follows:

"It shall be unlawful for any person knowingly or intentionally to use in the course of the manufacture or distribution of a controlled substance a registration number which is fictitious, revoked, suspended or issued to another person."

Another objective of the conspiracy as alleged in the indictment is to obtain controlled drug substances by misrepresentation, fraud, forgery, deception or subterfuge in violation of Section 843(a)(3), and that statute provides in pertinent part as follows:

"It shall be unlawful for any person knowingly or intentionally to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception or subterfuge."

The third alleged objective of the conspiracy is to distribute or possess with intent to distribute controlled drug substances in violation of Section 841, and that statute provides in pertinent part as follows:

"Except as authorized by this subchapter it shall be unlawful for any person knowingly or

intentionally to manufacture, distribute or dispense or possess with intent to manufacture, distribute or dispense a controlled substance."

You must find that it was an objective of the conspiracy to do at least one of those things, that is, to violate at least one of those laws. It is alleged that the conspiracy had three objectives to the violation of those three laws, but it is necessary for you to find that at least one of them was an objective of the conspiracy.

As I already told you, it is not necessary for the Government to prove the success of the conspiracy. Success or failure in the alleged undertaking to illegally obtain and distribute controlled substances is not material and is not an element of the crime of conspiracy.

As to the third element, defendants' participation or membership in the conspiracy:

If you conclude that a conspiracy as charged did exist and that at least one of the objectives of the conspiracy that is alleged has been proved, then you must next ask yourself whether the particular defendant you are then considering was a participant in the conspiracy, that is, a member of the conspiracy.

To find that a defendant participated in the

conspiracy you must upon all the evidence be satisfied beyond a reasonable doubt that that defendant, aware of its purpose, or at least one of them, was a willing participant with the intent to advance that purpose and that he joined the conspiracy with a specific criminal intent, that is, with a deliberate purpose to violate the law as alleged relating to phendimetrazine and phentermine.

In determining whether the defendant became a member of the conspiracy you must determine not only whether he participated in it, but whether he did so with knowledge of its unlawful purpose. Did he join with an awareness of at least some of the basic aims and purposes of the conspiracy?

In order to find that a defendant is a member of the conspiracy it is not necessary for the Government to prove that that defendant knew every detail of the conspiracy and all of its actors. It must prove, however, that he knew at least one other member and agreed with that member to violate the law.

Knowledge is a matter of inference from facts proved. To have guilty knowledge the defendant need not know the full extent of the conspiracy and all of its activities. Indeed, each member of the conspiracy may perform separate and distinct acts at different times

and different places. It is not necessary for the Government to prove that all members of the conspiracy knew all other members of the conspiracy in order to find that a conspiracy existed or that a particular defendant became a member of the conspiracy.

I want to caution you that mere association with a wrongdoer does not make one a member of a conspiracy. Nor is knowledge of some unlawful activity without participation sufficient. What is necessary is that the defendant participate with knowledge of at least some of the purposes of the conspiracy and with specific intent to aid the accomplishment of those unlawful ends.

If you find that the defendant participated in the conspiracy, then, however limited his role in furthering the objectives of the conspiracy, he is responsible for all that was done in furtherance of the conspiracy before he became a member and during its continuance. Once you are satisfied beyond a reasonable doubt that a conspiracy existed and that the defendant was a member, then the acts and declarations of any other persons whom you also find were members of the conspiracy made by such co-conspirators during its existence and in furtherance of its objectives are considered the acts and declarations of the defendant so found to be a member even though he was

not present.

Now we come to the fourth and final element which you must find and that is an overt act. I have already mentioned that the fourth essential element of the crime of conspiracy is that an overt act intended to effect the object of the conspiracy be committed by at least one of the co-conspirators after the unlawful agreement has been made here in the Southern District of New York.

An overt act is any step, action or conduct which is taken to achieve, accomplish or further the objective of the conspiracy. The purpose of requiring proof of an overt act is that while parties might conspire and agree to violate the law, they may change their minds and do nothing to carry their agreement into effect, in which event it would not constitute an offense.

The overt act need not be criminal in and of itself and it need not be the very crime which is the objective of the conspiracy. I have read to you the various overt acts listed in the indictment, and there are nine of them. An overt act may be an act which is innocent on its face but it must be of such character that it furthers or promotes or aids and assists in accomplishing the purpose of the conspiracy.

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For example, for Martin Weiner to pay Charles Fernald $4475 in cash and to receive 800,000 phendimetrazine tablets, as alleged in the second overt act, upon its face may appear to be innocent, but as the Government contends, this payment and receipt of phendimetrazine was a part of a scheme to illegally obtain phendimetrazine by misrepresentation and forgery and to illicitly distribute the drug.

The Government must prove this contention and in this case it must prove that this overt act did in fact occur and that it did occur here in Manhattan, which is a part of the Southern District of New York. It is not necessary for the Government to prove every single overt act alleged in the indictment. As I have said, it must in this case prove that particular one, that is, overt act No. 2, and it must also prove that it was an overt act in furtherance of the conspiracy alleged in this indictment.

It is not necessary for the Government to prove that each member of the conspiracy committed or participated in a particular overt act, since the act of any member done in furtherance of the conspiracy becomes the act of all other members. Also, the Government is not required to prove each of the overt acts, as I have

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said. It is sufficient if it proves the commission of at least one overt act in the Southern District of New York, which includes Manhattan, at or about the time alleged.

An overt act need not have occurred at the precise time alleged in the indictment. However, you must find that the overt act, and in this case act No. 2, occurred no earlier than March, 1973 and no later than March, 1976.

If you find that a defendant participated in the conspiracy, as I have said, then however limited you find his role in furthering the conspiracy, he is responsible for all that was done in furtherance thereof and during its continuance. And, as I have said, once you are satisfied beyond a reasonable doubt that a conspiracy existed and a defendant was a member, then the acts and declarations of any other person you also find was a member of the conspiracy made by such conspirator during the conspiracy's existence and in furtherance of its objectives are considered the acts and declarations of any defendant so found to be a member, even though he was not present when the act occurred.

While the indictment charges that the conspiracy existed from on or about March 1, 1973 up to the

date of the filing of the indictment, which is March 12, 1976, it is not essential that the Government prove that the conspiracy started and ended on or about those specific dates. It is sufficient if you find that in fact a conspiracy formed and existed for some substantial time within the period set forth in the indictment.

Some conspirators may play major roles while others play minor roles. The guilt of a conspirator is not governed by the extent or the duration of his participation, or by whether he played a greater or lesser role in the conspiracy. It is not required that a person be a member of the conspiracy from its very start. He may join it at any point during its progress and be held responsible for all that had been done before he joined and what may be done thereafter during its existence and while he remains a member.

If you find that the Government has failed to establish beyond a reasonable doubt any one of the four elements of the crime of conspiracy which I have just enumerated and discussed in greater detail for you, then you must find the defendant not guilty of the charge of conspiracy. On the other hand, if you should find that the Government has sustained its burden of proving each and every one of the four elements of the crime of con-

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spiracy which I have just enumerated and discussed as to a particular defendant, beyond a reasonable doubt, then you may convict the defendant on the conspiracy count.

At this time we are going to recess until 2.30 for lunch, after which the Court will continue charging the jury.

The jury is excused now. I think your lunch has been brought to the jury room so that you don't have to go out.

(The jury left the courtroom.)

THE COURT: We will recess now until 2.30.

MR. TIMBERS: Your Honor, there are several points I have with regard to instructions you have given the jury up to this point. I assume the defendants probably have some points also. It occurs to me that it might be appropriate to take those up prior to the time the Court resumes charging the jury so that if corrections have to be made, they can be made and not call undue attention to those points.

THE COURT: All right.

MR. TIMBERS: Perhaps I should start with my point. My major point has to do with venue on Count 1. The Court, apparently misled by the defendants' request for a venue charge on Count 1, told the jury that the only

overt act alleging venue in the Southern District of New York is overt act No. 2. In fact, there is proof of overt acts 3, 4 and 5, that those acts took place during telephone calls in which Mr. Fernald was on the telephone in the Southern District of New York and therefore it is the Government's position that it need only prove one of those overt acts 2, 3, 4 or 5 and is not confined solely to overt act No. 2.

THE COURT: All right. Do you have anything further?

MR. TIMBERS: The only other point I have, your Honor, I think -- in that connection your Honor misstated herself in that I think you said the agreement had to be in the Southern District of New York. I think that was an inadvertent misstatement. But in discussing venue, particularly in connection with the overt acts, I think you started off by saying that the jury had to find that the agreement was in the Southern District of New York.

THE COURT: I did? I don't recall that.

MR. TIMBERS: I'm sure it was inadvertent.

THE COURT: I don't think that I said anything of that nature until I got to the overt act section, but I'll make it clear.

MR. TIMBERS: I think this was a preliminary

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statement you were making to the jury before you started explaining what an overt act was, and I think you said, just in passing, that the --

THE COURT: Just a moment.

MR. TIMBERS: -- that the Government had to prove that the agreement was made in the Southern District of New York.

THE COURT: Just a moment.

No, I guess it is the way the sentence was worded, which reads as follows:

"I have already mentioned the fourth essential element of the crime of conspiracy, which is that an overt act intended to effect the object of the conspiracy be committed by at least one of the co-conspirators after the agreement has been made here in the Southern District of New York."

Yes, that could lead them to believe that the agreement had to be made in the Southern District of New York, so I'll correct that.

MR. TIMBERS: My other point has to do with the similar act instructions. It is the Government's position that there was other similar act testimony in this case not introduced to prove intent. The testimony --

THE COURT: The one with respect to Pastor --

Weiner, was that to prove intent?

MR. TIMBERS: Yes.

THE COURT: With respect to the others, I ruled at least twice that I didn't see those as similar acts.

MR. TIMBERS: I simply want to state for the record that the Government's position is that those are similar acts that go to show a course of conduct, an habitual method of proceeding, but I don't think that there is any need for a special instruction on similar acts with regard to that type of similar act testimony. It is a matter --

THE COURT: With respect to your first objection on the overt acts, I believe that I said-- but if I didn't, I'll correct it -- that they had to find at least one of the overt acts occurred here in the Southern District of New York. I don't believe that I said that was the only act, did I?

MR. TIMBERS: My recollection is, your Honor, that you did say that the jury had to find that overt act 2 was committed and I assume that the reason you said that was because that is the only --

THE COURT: That is the only one that the indictment indicates, you see. It occurred in the

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Southern District of New York.

Now, if the jury should send for this you are assuming that they are going to recollect that that telephone call occurred in Manhattan without the indictment having said so, so to make it clear to them that they have to find at least one of these overt acts having occurred in Manhattan, I pointed to that overt No. 2 and said they must find that that occurred.

MR. TIMBERS: I think the problem could occur this way:

Suppose the jury should decide that overt No. 2 did not occur. The instruction you have given the jury tells them that they must acquit at that point on the conspiracy charged, but I don't think that that is the way the law provides for the determination because in fact there is evidence that overt acts 3, 4 and 5 occurred in the Southern District of New York and I think it is improper to instruct the jury that if they find overt No. 2 did not occur, then that is the end of the question, they must acquit. I think perhaps the proper way to state it would be that the jury must find that one of the overt acts did occur in the Southern District of New York. I don't see any need to specify anything else. However, if the defendant should wish something

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else referring to specific counts the Government has no objection. However, I think to specify Count 2 as being the only count the jury can consider on venue, when in fact there are other counts that do have the support of testimony showing that they occurred in the Southern District of New York --

THE COURT: As to that payment there was testimony that that occurred in Pennsylvania Station?

MR. TIMBERS: No, that is the transaction that occurred at Mr. Fernald's office. Mr. Weiner drove up to New York City and the drugs were brought down by the boy on the cart and Mr. Fernald took them off the cart and put them in Mr. Weiner's car.

THE COURT: In any event, that is, as I have said, the only one here which clearly indicates to the jury that it occurred In Manhattan. I don't see why that could not have been added to 3 or 4 if you say that is what the facts are. The others occurred elsewhere, is that it?

MR. TIMBERS: Yes. I think we may have so alleged in the bill of particulars. I'll have to take it out.

In any case, the fact is that there is proof that these telephone calls were to the Southern District

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of New York and I don't think that it is proper to tell the jury that if you find that overt act 2 did not occur, then you have to acquit on this count when in fact the jury can convict if they find that overt acts 3, 4 and 5 occurred in the Southern District of New York and there is --

THE COURT: As I have indicated, I believe that the instruction to them was that they have to find at least one overt act occurred here in Manhattan and that this particular overt act is alleged to have occurred in Manhattan and they have to find that, if it did in fact occur.

Do you have anything else?

MR. TIMBERS: I have no further points, your Honor.

THE COURT: Did you have something, Mr. Cooper?

MR. COOPER: Yes, I have several, your Honor.

THE COURT: All right.

MR. COOPER: Your Honor, I am assuming that pursuant to the rule I am making my exceptions to at least that portion of the charge that the Court has given us so far.

THE COURT: Yes.

MR. COOPER: And that I will havean opportunity after the rest of the charge to make further exceptions if

I have any more exception.

On at least five occasions, especially at the beginning of the Court's charge, the Court talked in terms of guilt or innocence, that it was the province of the jury to determine the guilt or the innocence of the defendants. I noted that at least five times, that the Court made references in that language. I don't believe that the Court corrected that in its charge on reasonable doubt or presumption of innocence. The jury does not determine the guilt or the innocence --

THE COURT: They don't have to find in their verdict now the defendants either guilty or not guilty?

MR. COOPER: That is different, but when your Honor says guilt or innocence the jury assumes they have to find the defendant is guilty or innocent, but they don't have to find innocence the way most people understand it. What they have to find is guilt or that the Government has not proven the defendant guilty beyond a reasonable doubt. The Court referred to that at least five times. I don't think the Court ever corrected that, at least so far in the instructions.

THE COURT: I don't understand the objection.

MR. COOPER: What I am saying, your Honor, is that the jury's task is not to say Mr. Pastor is guilty

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or Mr. Pastor is innocent. When a juror or when a laymen thinks of the term innocence they mean "I find he did not do this."

THE COURT: They do have to return, as I have told them, a verdict of guilty or not guilty.

MR. COOPER: Guilty or not guilty is different.

THE COURT: Is different from --

MR. COOPER: Guilty or innocent. The Government has to prove the defendant guilty or if they don't prove it beyond a reasonable doubt the jury returns a verdict of not guilty. When you say guilty or innocent it seems to the jury that the defendant has to show that he is innocent.

THE COURT: I don't understand the objection.

What else do you have?

MR. COOPER: Your Honor, when you were explaining that the jury has to determine issues of fact and that issues of fact occur when one witness testifies one way -- let me withdraw that one, your Honor.

When you were explaining accomplice testimony you did not warn of the dangers of accomplice testimony.

THE COURT: I'm not going to hear that. The charge did warn of the dangers of accomplice testimony.

MR. COOPER: Your Honor, in discussing the

motive of a witness you didn't mention cooperation of the witness with the Government. We requested that both witnesses, and I'm talking about Fernald and Berry, stated they were cooperating with the Government and the Court said it would in some way list their responsibilities or the effects of whatever may happen to them and the Court failed to mention that.

THE COURT: I did charge that they should consider any motive the witnesses may have for testifying for the Government.

MR. COOPER: Yes, but the Court didn't point out one of the motives, one of the reasons --

THE COURT: What else do you have?

MR. COOPER: On the charge regarding identification, your Honor, I believe the Court patterned the charge on the one that we submitted, but the Court in reading the charge or in charging the jury left out the paragraph we had relating to the suggestibility of a single photo ID and did not charge the substance of what that paragraph in our request stated in any other manner to the jury. I believe that the Court should have done that. That is part of the pattern charge that we adapted our charge from, your Honor.

THE COURT: I believe that I did. As I told

you initially, I wasn't adopting your exact language, but I would adopt the substance of your request and I believe I did.

What else do you have?

MR. COOPER: Your Honor, in charging as to the effective weight of any confessions or incriminating statements that may have been made, the Court in essence read the charge to the jury that we requested but, significantly, left out that sentence which follows. It is just one sentence, if I may read it:

"If you decide they are entitled to no weight" -- speaking of the statements allegedly made -- "but you find they were obtained as a result of overbearing on the part of the Government agents, you may disregard them totally."

Other than that sentence, the Court read the entire charge. I think the Court should have read that sentence also.

THE COURT: What else do you have?

MR. COOPER: In defining or stating to the jury that there are two kinds of evidence, direct and circumstantial evidence, the Court did not define circumstantial evidence sufficiently in that you left out the admonition that if there is more than one analysis to be

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given to inferences as to circumstantial evidence presented, and one analysis is that of guilt and the other is not of guilt, then the jury must accept the one which points to the lack of guilt.

THE COURT: Two inferences?

MR. COOPER: If there are two inferences.

THE COURT: The Court of Appeals in this Circuit has expressly ruled on that in United States against Taylor and has said it is not required.

MR. COOPER: Your Honor, this may be premature because I know the Court isn't finished, but I believe you may have finished your charge as to conspiracy. I don't believe you told the jurors that they have the right and the obligation to determine who the co-conspirators are and they don't have to be bound by the allegations in the indictment.

THE COURT: All right, anything else?

MR. GOLDMAN: Your Honor, he can't read my writing.

When discussing circumstantial evidence, the Court did not indicate that proof that the drugs in question here were phendimetrazine and phentermine was established or attempted to be established by circumtantial evidence; that there was no direct evidence in the case

with regard to the identification of the drugs but the existence and that was established by circumstantial evidence, in other words, invoices, but no direct evidence in the case, your Honor. I don't think the jury understrands that there was no direct evidence with regard to the identification of the drugs.

THE COURT: Anything else?

MR. GOLDMAN: Yes, your Honor.

On the three occasions when the Court referred to Dr. Johnson's BNDD number it characterized it as suspended. In fact it was expired. Suspended indicates, your Honor, that there was some affirmative action taken to remove that and it cut directly across the charge in this case. It expired and it could have been renewed at any time for $5.

That is all, your Honor.

THE COURT: Anything else, Mr. Sparks?

MR. SPARKS: No, your Honor. I will just join in those objections that would be applicable to my client. I was not involved in the confession objections, but the other objections I would join in.

THE COURT: All right.

MR. TIMBERS: I don't want to argue any further, but I would like to hand up to the Court the Government's

bill of particulars which does spell out that --

THE COURT: I'm not going to change it, Mr. Timbers. As I have indicated to the Jury, they have to find that one overt act occurred here in Manhattan and that is the one that the indictment indicates and they are going to have to find that.

All right, we will recess until 2.30.

(Luncheon recess.)

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AFTERNOON SESSION
2:50 p.m.

(Jury present)

THE COURT: Ladies and gentlemen, as you recall before the luncheon recess I had discussed with you count 1 of the indictment which is the conspiracy count and I pointed out to you that conspiracy consists of an agreement to violate the law and an overt act done by one of the co-conspirators in furtherance of that objective.

I want to clarify something, and that is that it is not necessary to find that the agreement was made in New York in this case, but as I pointed out it is necessary for you to find that at least one overt act occurred in New York. And I pointed to the overt act in the indictment, overt act two which the indictment said occurred in Manhattan.

Of course, you may find some other overt acts in fact occurred here, but that one in the indictment plainly indicates -- it alleges anyway -- occurred here in Manhattan. And you would have to find that that was so.

Now we come to the substantive crimes, as we call them.

There are five substantive crimes charged in this indictment in counts 2 through 6.

Before reading and discussing those counts, I want to instruct you that there are two legal theories on which you may find the defendants guilty or a defendant guilty of a particular substantive crime.

The first theory is a part of the law of conspiracy, which I have just discussed for you, and is completely dependent upon a finding by you that the particular defendant you are then considering is guilty of the crime of conspiracy.

In other words, only if you find that the particular defendant you are then considering is guilty of count 1, the conspiracy charge, do you consider this first theory.

The second theory is the law relating to aiding and abetting the commission of a federal crime.

I shall discuss the conspiracy theory first.

You may find either or both of the defendants guilty as to any or all of the substantive counts 2 through 6 on the theory that these were all crimes committed by Charles Fernald, a co-conspirator, in furtherance of the conspiracy for which, under the law of conspiracy, these defendants are responsible. And, of course, you

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must find that Charles Fernald was a member of the conspiracy or a co-conspirator as alleged in the indictment.

Therefore, if you find beyond a reasonable doubt that the substantive offense alleged in any given count was committed in the Southern District of New York by Charles Fernald and that he was a member of the conspiracy, that the particular defendant you are considering was then a member of the conspiracy and that the acts which constitute the offense were done here in the Southern District of New York in furtherance of a portion of that conspiracy of which the defendant was a member and that the defendant might reasonably have foreseen that those acts would be done, then you may find the defendant is guilty of that particular count, even though he did not otherwise personally participate in the acts constituting the offense, or did not have knowledge of them at the time committed.

I charge you further that as a matter of law the defendant Weiner can only be found guilty of counts 2, 3, 4 and 6 on this particular theory since the government has failed to present such evidence as to these counts from whichyou can find defendant Weiner guilty either on the aiding and abetting theory I shall discuss

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later, or for having actually personally committed the offense charged in counts 2, 3, 4 and 6.

The second theory on which you can find a defendant guilty of a substantive count stems from the federal aiding and abetting statute. And the indictment charges with respect to eachof these counts that the statute violated is title 21, United States Code, Section 843A3 which I will read again when I come to the discussion of these counts, and title 18, United States Code, section 2.

Title 18, United States Code, section 2, is the federal aiding and abetting statute, and that statute provides in pertinent part as follows:

"Whoever commits an offense against the United States, or aids, abets, counsels, commands, induces or procures its commission, is punishable as a principal. Whoever wilfully causes an act to be done which if directly performed by him or another would be an offense against the United States is punishable as a principal."

Defendant Pastor can be found guilty as to any or all of these counts even if you find that he did not directly commit the crimes in question. And defendant Weiner can be found guilty as to count 5 of the indictment, even if you find that he did not directly commit the

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crime in that count.

If you find beyond a reasonable doubt in regard to these counts that the defendant in question aided and abetted the commission of the crime by the witness Charles Fernald, who you must find committed those crimes here in the Southern District of New York. In other words, it is not necessary for the government to show that it has established all the elements of the particular count as to the defendant in question, or that the said defendant physically committed the crime himself here in the Southern District of New York.

Accordingly, you may find defendant Pastor guilty of any or all of the substantive counts charged if you find beyond a reasonable doubt that Charles Fernald actually committed the offense charged in the particular count and that the defendant Pastor aided and abetted Fernald.

Similarly, as to count 5 only, you may find defendant Weiner guilty if you find beyond a reasonable doubt that Charles Fernald committed the crime charged in count 5 and that defendant Weiner aided and abetted him in its commission.

There is no particular rule as to what acts of a defendant would make him an aider and abetter. It

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is enough, however, if you find that a defendant knowingly associated himself in some manner with the illegal venture, actually participated in it as something he wished to bring about, or that he sought by his actions to make succeed.

In this connection, you may consider whether the defendant had a stake in the venture. In other words, the law is that one who aids and abets another with knowledge of the unlawful nature of the offense is just as guilty of that offense as if he committed the offense himself.

To find a defendant guilty of aiding and abetting, you must, of course, find something more than mere knowledge on his part that a crime has been committed.

Thus, a mere spectator at a crime is not a participant.

Consequently, in order to find a defendant guilty of aiding and abetting, you must find that the particular defendant you are then considering with knowledge as I said of the unlawful purpose in some way associated himself with the illegal activity and that he knowingly participated in it as something he wished to bring about and that he knowingly by his actions endeavored to make it succeed.

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Now I shall read each of these counts, and they are all similar, except for the date and the particular drug involved.

Count 2 reads as follows:

"In or about July, 1973, in the Southern District of New York, Edward Pastor and Martin Weiner, the defendants, unlawfully, intentionally and knowingly did obtain possession of schedule 3 controlled substances, to wit approximately 100,000 phendimetrazine capsules by misrepresentation, fraud, deception and subterfuge."

And, as I said before, the indictment cites title 21, United States Code, section 843A3 and title 18, United States Code, section 2.

Count 3 is similar, except for this. It says "In or about August, 1973." And the drug alleged to be involved there is approximately two million phendimetrazine tablets.

Count 4 is the same, except that it alleges "In or about September and October, 1973."

And the substance alleged to be involved there is approximately 250,000 phendimetrazine capsules.

Count 5, the date is from October '73 up to and including June, '74, and the substance alleged to be involved there is approximately 980,000

phendimetrazine capsules.

Count 6 is the same, except for the date, and that is it alleges that this occurred from April, '74 up to and including June, '74, sometime in that area, and the substance alleged to be involved there is approximately a million 080 tablets of phentermine.

Title 21, United States Code, section 843A3, which is cited here as the law that was violated reads in pertinent part as follows -- and I read this earlier -- "It shall be unlawful for any person knowingly or intentionally to acquire or obtain possession of a controlled substance by misrepresetnation, fraud, forgery, deception or subterfuge."

In order to find a defendant guilty, as I said, of one of these substantive counts, you must find beyond a reasonable doubt that the government has proved each of the following essential elements:

First, that on or about the dates specified in the date you are considering Charles Fernald acquired or obtained possession of a substance.

Second, that the substance he acquired or obtained was in fact a controlled substance.

Third, that Fernald acquired or obtained the controlled substance by misrepresentation, fraud, forgery,

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deception or subterfuge.

And, fourth, that Fernald did so knowingly and wilfully.

(Continued on next page)

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Now I want to discuss each one of these elements in greater detail. The first element the Government must establish is that Fernald acquired or obtained possession of a substance. This element is satisfied by proof that Fernald came into possession of a substance.

There are two kinds of possession recognized in the law, actual possession and constructive possession. The person who knowingly has direct physical control over a thing at a given time is then in actual possession of it. A person who though not in actual possession knowingly has both the power and intention at a given time to exercise dominion and control over a thing, either directly or through another person or persons, is then in constructive possession of it.

The second element that the Government must establish is that the substance the defendant obtained by misrepresentation was a controlled substance at the time that he obtained it. I instruct you as a matter of law that phendimetrazine has been a controlled substance since June 15, 1973 and that phentermine has been a controlled substance since July 6, 1973.

In considering the evidence which has been submitted to you, one of the determinations which you will have to make is whether the substance involved in each of

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the alleged transactions in Counts 2, 3 and 6, which transactions serve as the basis for the various counts, was in fact phendimetrazine or phentermine as alleged in the indictment. So that before you can find a defendant guilty of the particular count you must find beyond a reasonable doubt that the substance involved was in fact phendimetrazine or phentermine as alleged in the particular count.

Now we come to the third element. The third element that the Government must establish is that Fernald acquired the controlled substance by misrepresentation, fraud, forgery, deception or subterfuge. The language describing this element is almost self-explanatory. For instance, to misrepresent means to make a false or misleading statement or representation. The Government contends that the defendants and Fernald did this by falsely representing that they were purchasing pendimetrazine and phentermine from Dr. Horace Johnson when in fact Dr. Johnson had never requested these drugs, and the defendants were in fact acquiring the drugs in order to distribute them on the illicit market.

Similarly fraud is a generic term which embraces all the many and varied means which human ingenuity can devise to gain advantage by false represent-

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ations, suggestion or suppression of the truth.

The meaning of the other words in this element, forgery, deception, subterfuge, are self-explanatory.

Now, the Drug Enforcement Administration has the duty under the law to regulate traffic in the drugs in question in this case and if the drugs are obtained by misrepresentation or fraud or forgery, then in this case it is the Government to whom the misrepresentation or fraud or forgery is made.

The fourth element, knowingly and wilfully -- I initially discussed those terms for you before I discussed any of the substantive counts.

If you find that the Government has failed to prove any one of these four essential elements of a substantive crime beyond a reasonable doubt, then you must acquit the defendant of that particular count. On the other hand, if you find that the Government has proved each and every one of these essential elements beyond a reasonable doubt, then you may convict the defendant on that particular count.

Now, as I have said, what I have said applies to each one of these counts because they are all similar except for the date.

Now, the most important part of this case is

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the part which you now as jurors are about to play, because it is for you and you alone to decide whether a defendant is guilty or not guilty as to each count of the indictment. I know that you will try the issues that have been presented to you according to the oath which you have taken as jurors. In that oath you promised that you would well and truly try the issues joined in this case and a true verdict render. I suggest to you that if you follow that oath and try the issues without combining your thinking with any emotions you will arrive at a new and just verdict.

Now, it must be clear to you that once you get into an emotional state and let fear or prejudice or bias or sympathy interfere with your thinking, then you will not arrive at a true and just verdict.

The jury is not to consider or in any way speculate about the punishment which a defendant may receive if he is found guilty. As I told you before, it is the function of a jury in a criminal case to determine the guilt or innocence of a defendant on the basis of the evidence and the Court's instructions as to the law. It is then for the Court alone or the Judge who has the duty of determining the sentence, if there is a conviction. So that possible punishment should not

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enter into your deliberations, because it is not part of the jury's function to determine what the punishment would be, if there is a conviction.

As you deliberate, ladies and gentlemen, please be careful to listen to the opinions of your fellow jurors as well as to ask for an opportunity to express your own views. No one juror should hold the center stage in the jury room and no one juror may control or monopolize the deliberations.

If after listening to your fellow jurors and if after stating your own view you become convinced that your view is wrong, do not hesitate because of stubbornness or pride of opinion to change your view.

On the other hand, do not surrender your honest conviction solely because of the opinion of your fellow jurors or because you are outnumbered.

You understand, of course, that in a Federal criminal case of this kind your verdict as to each count as to each defendant must be a unanimous verdict, and the form of your verdict is either guilty or not guilty. You will endeavor to arrive at a separate verdict as to each count for each defendant provided you can do this reasonably and consistently with the conscientious conviction of each and every one of you. You may find

each defendant guilty as to each count with which he is charged. You may find each defendant not guilty as to each count with which he is charged. You may find a particular defendant guilty on some counts with which he is charged and not guilty on other counts with which he is charged.

I remind you that guilt is personal and that you must consider the evidence against each defendant separately.

If you are unable to agree on a verdict as to one or more of the counts as to one or more of the defendants you may not compromise by agreeing to a guilty verdict on one or more of the counts and a not guilty verdict on the others. In other words, your verdict as to each count must be a unanimous verdict of all the jurors.

When you retire to the jury room to deliberate you may send for any of the exhibits which you would like to review, any exhibit which was actually received in evidence. In addition, you may have any of the testimony read back. We can't send in the transcript, but if you want to hear a portion of some testimony, if you will send out a note the reporter will find it and we will read it to you. The same with an exhibit. If you want to see an exhibit, just send out a note.

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Don't speak to anybody about anything. The marshal will be there. You just hand the marshal a note.

Now, you are instructed that you are not to reveal the standing of the jurors, that is, the split of the vote, if that should occur, to anyone at any time, including the court, during the course of your deliberations. Of course, when you finally have reached a verdict the foreman should notify the marshal or you can send out a note to that effect, that a verdict has been reached.

All right, you may retire to the jury room for a few minutes before you finally commence Your deliberations.

(The jury left the courtroom.)

THE COURT: All right, Mr. Timbers, do you have any exceptions to the charge?

MR. TIMBERS: Yes, your Honor.

On the aiding and abetting charge, I believe the Court instructed the jury that they should consider aiding and abetting in the context of whether the defendants aided and abetted Mr. Fernald.

The Government's theory on aiding and abetting is that Mr. Pastor was the principal and that he may have in certain instances where Mr. Weiner did not actually

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receive or make the misrepresentations -- Mr. Weiner may have aided and abetted the acquisition of drugs by handling the payments and the delivery. Therefore, the Government would request that where the Court said in the aiding and abetting instruction that if the jury finds that Mr. Fernald did it and either of the defendants assisted him, the Government would simply request that the Court charge the jury:

If one of the defendants did the act and he was assisted by the other defendant, that that is aiding and abetting.

THE COURT: That is denied.

Do you have anything else?

MR. TIMBERS: The same point in the Pinkerton charge, your Honor. The Pinkerton charge says that if Mr. Fernald did it and either of the defendants assisted him, then the jury can find that the defendants are guilty under Pinkerton. The Government's theory is that Mr. Pastor did --

THE COURT: The Court said that if the jurors found that Mr. Fernald did it in furtherance of the conspiracy these defendants, if they are found guilty of conspiracy, are liable for that act.

MR. TIMBERS: That is my point, your Honor.

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The Government's theory is that Pinkerton is applicable here to the extent that Mr. Weiner did not actually make the misrepresentations and handled the drugs, he is guilty because his co-conspirator, Mr. Pastor, did it. The Government does not claim that it can obtain a conviction by proving that Mr. Fernald did it. I guess we contend that, but our primary claim is that Mr. Pastor did it nd he was assisted, aided and abetted by Mr. Weiner, and that also Mr. Weiner is guilty because he was, under Pinkerton, a co-conspirator of Pastor.

I think there is some confusion --

THE COURT: Aren't you kind of overlooking the venue problem in all this?

MR. TIMBERS: No, I'm not. I think there is some confusion in the charge on the elements of the crime and the venue. For purposes of venue, the Government has consented that Mr. Fernald was the agent of the defendants, but that is only for purposes of venue. As far as the elements of the crime is concerned, the Government's contention is that Mr. Pastor did it. On certain of the counts Mr. Weiner may have aided and abetted, similarly, Mr. Pastor as co-conspirator who committed the crimes on certain of the counts. However, Mr. Weiner may be guilty because his co-conspirator, Mr. Pastor,

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committed the crime.

The issue of venue is completely separate.

THE COURT: Yes.

Do you have anything?

MR. GOLDMAN: Yes, your Honor, I have one that I think is extremely grave, your Honor.

With regard to the first essential element of the substantive counts your Honor charged that the jury need only find that Charles Fernald had possession or obtained these drugs. It was limited solely to that. There wasn't a charge given at any time that they had to find that either of these defendants ever obtained possession nor was there any curative qualification as to Mr. Fernald's possession in the form of: If you find they acted together, then it is sufficient if Fernald did it, but first you must find that they acted together. The possesion was strictly, tracking the charge, your Honor, that if you find that Charles Fernald obtained possession and if you find that the drug was phendimetrazine and if you find the obtaining was by fraud wilfully and knowingly, then you find these defendants guilty. That is the sum total of the charge your Honor gave with regard to the substantive counts, and I suggest, your Honor, that I think if genuinely misleads the jury to

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believe all they need find is that Fernald acquired possession; that at no time did the defendants acquire possession, or, in conjunction with that, that Fernald's obtaining it was with the guilty knowledge of procurement of these defendants, and I respectfully ask that that be corrected.

THE COURT: Do you have anything else?

MR. SPARKS: I join in that one, your Honor.

THE COURT: All right.

MR. TIMBERS: That is essentially the Government's point also, that whenever in the request that the Government submitted Mr. Fernald's name was -- that the impression given to the jury may be a misleading impression and that what should be done here is to track the language in the Government's request, in this one particularly, that the first element the Government must establish is that a defendant acquired or obtained possession of a substance.

THE COURT: Anything else?

MR. COOPER: Your Honor, I wish to except for the record to all the charges that we requested as to as to which the Court previously advised us it had rejected, and at this time we except to the Court not giving those charges.

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In addition to the first theory that the Court charged the jury on with respect to the substantive counts, the Court labeled it the conspiracy theory, which is the Pinkerton theory, I imagine. We except to that, your Honor, because of the same reasons we do as to the second theory. The Court charged that if they find Mr. Fernald committed the crime they can find that the defendants were liable, and I think that is not true as per the Government's theory as it related to you yesterday and again as Mr. Timbers related it today.

I think as a matter of law the Court can't find Mr. Fernald committed the crime as the principal either in the Southern District or any place else, and, as we said yesterday -- I won't repeat our entire argument of yesterday -- I believe that that charge is inaccurate in any event as it pertains to this case, that the Pinkerton theory is inaccurate as it pertains to this case in that Mr. Fernald was not a principal committing the crime here in the Southern District.

Related to that, your Honor, I don't believe the Court has sufficiently charged venue with respect to the substantive counts and also, your Honor, although the Court charged that if the jury found Mr. Fernald committed the first two elements of the substantive count, the

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Court stated in defining the misrepresentation element that they could find either Fernald or the defendants perpetrated that element of the crime and I think that that is not within either theory or any theory of the substantive counts.

Finally, yo9ur Honor, as we said yesterday, the Court charged that misrepresentation in this case can be on the Government in general and doesn't have to be perpetrated on any individual person. We rest on what we said -- if that can be deemed to be contained in our exceptions -- on what we said yesterday moving to dismiss and ask that that argument be deemed to be incorporated in these exceptions.

THE COURT: All right.

MR. SPARKS: I join in those exceptions.

MR. TIMBERS: May I just point out to your Honor that everybody has objected to the charge on aiding and abetting and the Pinkerton charge and for the same reasons, and I would ask the Court to reconsider that matter. I think we are creating an appellate issue and I think the solution to the problem is to adopt the language in the Government's request charge that if the defendants aided as principals and another defendant assisted, then you have aiding and abetting.

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THE COURT: Are all exceptions now noted on the record?

MR. GOLDMAN: Yes, your Honor.

MR. SPARKS: May I just ask a question?

You indicated earlier this morning, when we broke at 10.50 a.m., that we would have an opportunity to take up the objections to Mr. Timbers' summation after the charge. I don't know whether you wanted us to do that now.

THE COURT: All right, you can do that now.

MR. TIMBERS: Should we hear it now or after the jury goes out?

THE COURT: Let's see if we can't get it on the record and get it over with.

MR. SPARKS: The one that I just wanted to make a point about specifically with respect to myself and the defendant Weiner, your Honor, was the first point made by Mr. Cooper this morning and that was that Mr. Timbers said something to the jury in his summation that was absolutely not so and that was that the defendants, and specifically the defendant Weiner, ever claimed that these drugs were purchased for his pharmacy. There is absolutely no testimony as to that. There was absolutely nothing said in my opening remarks that would

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in any way admit anything of that nature or even any inclination of any defense or anything of that nature, and what Mr. Timbers said in his summation to the jury was absolutely false, your Honor.

THE COURT: All right.

Did you have something else, Mr. Cooper?

MR. COOPER: Yes, I do, your Honor, as to Mr. Timbers' summation. We object to the giving of testimony, in effect, by Mr. Timbers in his narration of the circumstances surrounding the sale by Mr. Fernald of controlled substances to a Mr. Erker. I believe almost everything that Mr. Timbers said in that regard is what Mr. Timbers may have known or may have learned outside the presence of this courtroom and refers to matters which this jury did not hear. Mr. Timbers, in effect, testified to what some of the circumstances were when he summed up to the jury.

In addition, your Honor, on three different occasions at least Mr. Timbers, in effect, tried to -- or whether he tried to or not, did attempt to shift the burden from the Government to the defendants. The first time he was talking about phone calls and he said, and I think it is a fairly accurate quote, referring to Mr. Pastor:

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"He has got to explain away the phone calls."

That would seem to shift the burden to Mr. Pastor to do something. He doesn't have to do anything.

Another attempt he made was making the same implication concerning the explanation of APA documents, and in another instance he made the same implication regarding invoices for prior orders to Dr. Johnson. Those are the extent of my objections to Mr. Timbers' summation.

There is one further thing. The Court has not indicated what it intends to do with regard to our objections to the aiding and abetting charge that the Court gave, but if the Court was inclined to follow Mr. Timbers' suggestion concerning charging in the pattern that Mr. Timbers has submitted to the Court in the Government's requests to charge, I think the Court is bound to charge, specifically to charge venue and to charge that a principal, and Mr. Timbers claims that Mr. Paster is a principal, cannot be found to have committed the crime in a District only an accessorial act occurred by an agent.

Mr. Timbers says his theory is that Mr. Fernald was only an agent. I think I clearly showed to the Court yesterday the case law which says that you cannot

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have venue where only an act of an agent is shown and if the Court does not dismiss for that reason, which I urge that it should do even at this point as to the substantive counts, then at least I think an instruction to the jury is necessary in that regard.

MR. SPARKS: One further point, your Honor:

Mr. Cooper made reference to Mr. Timbers making remarks about the defendants having to explain the phone calls. Likewise, a specific comment was made concerning Mr. Weiner having to explain about the phone calls and I would object to that, your Honor, as being totally improper and gets into the issue of the defendants not having to take the stand or offer anything, your Honor.

THE COURT: I think Mr. Timbers made clear that he was not saying that the defendants had to take the stand. What he was saying is that they could offer other evidence and that the Second Circuit has already ruled is proper, that is, to say that the defendant could show anything he wanted by somebody else or some other evidence by taking the stand.

Now, with respect to the matter mentioned this morning that Mr. Timbers injected into the case, that Mr. Pastor, when he was at the DEA office here in New York

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making certain admissions was doing so because he was looking for a deal with the Government, it seems to me that there is a proper inference that the jury could draw from the facts and circumstances in this case that that is what he was doing. It was the testimony of Fernald and Berry, both of whom were given suspended sentences and put on probation because of their cooperation with the Government, and the testimony of Mr. Vigna was to the effect that he was there giving a statement and the jury could properly infer that that was a statement given for that purpose or he was cooperating with the Government then or admitting his guilt in the hope of getting some kind of leniency.

(Continued on next page.)

As I pointed out earlier, there would be no real benefit to the defendant in rementioning that point. It would only emphasize it.

But, as I have said, that evidence is there so the remark is not as prejudicial as suggested.

Now, with respect to the other matter, I instructed the jury repeatedly that it was their recollection which governed as to certain facts

What I plan to do is to reemphasize to the jury that there are only two theories on which they can convict a defendant of the substantive count. One is the conspiracy theory, which I explained, or on aiding and abetting.

With respect to Mr. Weiner, I believe that I said that under the conspiracy theory he could be found guilty on counts 2, 3, 4 and 6, but actually 5 should have been included in that.

With that correction --

MR. TIMBERS: I am not sure that's right, your Honor.

THE COURT: On the Pinkerton theory.

MR. TIMBERS: Oh.

MR. GOLDMAN: Your Honor, may I be heard?

THE COURT: And only on five on the aiding

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and abetting theory.

Now, we are not going to be heard any further.

MR. GOLDMAN: Your Honor, this is very important. I have had not one chance to respond. I do not join with Mr. Timbers. He said we both agreed in our application to the Court. I do not agree.

THE COURT: We have been over this. You don't have to agree with Mr. Timbers. I am not saying you agree with Mr. Timbers.

MR. GOLDMAN: I want to make sure that point doesn't get lost.

THE COURT: What point?

MR. GOLDMAN: I am not offering a quarrel at this time in this context with regard to Mr. Timbers about aiding and abetting. My reference is to the possession, your Honor.

In other words, giving the aiding and abetting thing does not answer my objection. My objection is when it came to the substantive count the Court solely stated that the element of possession is satisfied if they found that Charles Fernald obtained the drugs. It gave no qualifications, nothing but that. That is my point, your Honor. Reiterating aiding and abetting just emphasizes --

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THE COURT: I have forgotten that point.

MR. GOLDMAN: I want to be sure, your Honor.

THE COURT: I made these comments. On aiding and abetting, the jury must find somebody else committed the crime and that the defendants aided and abetted in some respect.

MR. GOLDMAN: Would your Honor just connect that with possession? Because, believe me, your Honor, the jury is absolutely confused. I know because I sat here, your Honor, and I waited for the slightest connection to be made. It was never made.

I tracked the charge of the Court, your Honor. The charge was if Fernald obtained possession, if the drug was phendimetrazine and if Fernald made representations, your Honor, they may find these defendants guilty.

THE COURT: All right, you made your statement. Now we are going to bring in the jury.

(Jury present)

(Note handed to the Court)

THE COURT: All right. Ladies and gentlemen, with respect to the chart, I want to reemphasize at this point that with respect to counts 2 through 6 there are only two theories on which you can find a defendant

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guilty of a substantive count.

The first theory is theone that I called the conspiracy theory and is predicated on your finding the defendant you are then considering is guilty of conspiracy.

With respect to each one of those counts 2 thorugh 6 you may find a defendant guilty on that theory as I explained it.

When I was explaining it, I saiv as to Defendant Weiner he could be found guilty on those counts, except for 5, but I am now telling you that he can be found guilty on the conspiracy theory with respect to 5 also.

So that as to counts 2, 3, 4, 5 and 6 both defendants may be found guilty on the conspiracy theory if you first find that they are guilty of count 1.

The second theory was the aiding and abetting theory, and as to that theory defendant Pastor may be found guilty as to each of those counts on the aiding and abetting theory, but as to defendant Weiner only as to count 5.

With that clarification, you may commence your deliberations.

Will the clerk please swear the marshals.

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And I want to say that I have this note from the jurors which we will mark Court's Exhibit 1 as of this date, which reads as follows:

"Dear Judge Motley:

"We respectfully request to have the air conditioning turned off in the jury room. Many of the jury members find it unbearably cold.

"Yours truly, M. Weiskopf, foreman."

(Court's Exhibit 1 marked)

THE COURT: All right, we will ask the marshal to turn down the air conditioning so you don't freeze.

THE CLERK: I already called downstairs and they say the air conditioning is not on.

THE COURT: It's not on?

THE CLERK: I will call the manager again, Judge.

THE COURT: We may have to utilize the robing room as the jury room by putting the jurors in there and have the marshals guard that room.

You try it and let us know. If it's too cold for you, we'll switch you to the robing room where I don't believe it's that cold.

First of all, we'll excuse the alternate

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jurors, or the one alternate juror we have left.

Mrs. Vera Monteforte, on behalf of the citizens of the Southern District of New York, this Court thanks you for your service on this jury. I am sorry that you will not get an opportunityto deliberate with your fellow jurors after having sat through this trial, but I am afraid that that is often the fate of alternate jurors.

I am sure you realize that your service was essential in the event that another one of the regular jurors became incapacitated, as happened very early in this trial when we had to utilize the first alternate juror.

So you are excused now with the thanks of the Court.

Let me ask you, do you have anything in the jury room?

ALTERNATE JUROR: No.

THE COURT: Then, will you please leave through the main door here so that you do not run into any of the jurors.

The clerk informs me -- just a moment -- the clerk informs me you should go down to room 109 to get your service card.

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ALTERNATE JUROR: Thank you.

(Alternate juror discharged)

THE COURT: All right. At this time the clerk will swear the marshal.

(Deputy marshal sworn)

THE COURT: All right. The jurors may follow the marshal to the jury room

(The jury left the courtroom at 3:46 p.m., to commence deliberations)

MR. GOLDMAN: If I may, your Honor, may I note on the record the defendant objects to the further charge that was given in two regards, your Honor. First was a failure to clarify the previous charge with regard to possession -- singular -- and sold by Fernald, and, secondly, in giving the corrective charge at this time the Court emphasized solely the various means by which the defendants could be found guilty without giving sufficient balance to the other aspect normally associated with the methods by which one is found guilty.

For instance, there was no suggestion at first they must find beyond a reasonable doubt.

There was just, as delivered, an indication of divers ways of finding defendants guilty, your Honor,

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and it is overly stressed and unbalanced.

MR. SPARKS: I would join in that, your Honor.

THE COURT: All right.

MR. TIMBERS: Your Honor, one or two quick points. First of all, the objections the government made are objections that it made because it felt that there was a problem as far as the defendants' rights were concerned, and so far as those objections are not picked up by the defendants the government waives any objection.

In other words, what I am saying is that I think -- my reason for objecting to the request was that I thought some disservice had been done to the defendants, but the defendants had not picked up the full point of my objections and, therefore, to the extent that they haven't I waive them.

THE COURT: I don't know what that is intending to say, but I will say that the charge was given as it has been given becasuse of the venue problem presented in this case. And that is the explanation for the way the charge was given.

All right.

MR. GOLDMAN: We did not waive or give up any of the suggestions made by Mr. Timbers. My comment

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was --

THE COURT: Let's shorten all this by saying you don't waive anything, you don't give up anything, you can take everything up on appeal. You waive nothing.

MR. TIMBERS: Your Honor, on a different topic, the defendants objected to my summation. I would like to object to the defendant's practice of talking very loudly at the defense table while I was making my summation. It was quite loud. I suspect that the Court could probably hear it.

THE COURT: Yes, I rapped a couple of times for the defendants to keep quiet.

MR. TIMBERS: Finally, your Honor, could I ask what the Court's schedule is for this evening? How late do you expect to sit?

THE COURT: Well, until 11 o'clock and then have them taken home by bus and come back tomorrow morning, if necessary.

All right, gentlemen, I think that the jurors will send for some of the exhibits, probably Government's Exhibit 35, which lists all the exhibits, or some of the other major exhibits. And when the note comes out, I don't want to have the problem of trying to find the

JUDGMENT AND PROBATION/COMMITMENT ORDER

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
----------X
UNITED STATES OF AMERICA,

v.

No. 76 Cr. 253 (CBM)

MARTIN WEINER,

Defendant.
----------X

In the presence of the attorney for the government the defendant appeared in person on this date, July 26th, 1976, with counsel W. Donald Sparks, Esq.

PLEA: NOT GUILTY

There being a verdict of GUILTY.

Defendant has been convicted as charged of the offenses of possessing Schedule III controlled substance, to wit, phendimetrazine capsules and Schedule IV controlled substance, to wit, phentermine, by misrepresentation, fraud, forgery, deception, and subterfuge. (Title 21, U.S. Code, Sections 843(a)(3) and Title 18, U.S. Code, Section 2.) and conspiracy so to do. (Title 21, U.S. Code, Section 846) as charged in Counts 1, 5 and 6.

The court asked whether defendant had anything to say why judgment should not be pronounced. Because no sufficient cause to the contrary was shown, or appeared to the court, the court adjudged the defendant guilty as charged and convicted and ordered that: The defendant is hereby committed

to the custody of the Attorney General or his authorized representative for imprisonment for a period of SIX (6) MONTHS on counts 1, 5 & 6 to run concurrently with each other. Imposition of sentence is suspended. Defendant placed on probation for TWO (2) YEARS.

Fine of $3,000.00 on Count 1 to be paid within 30 days for date of judgment. Defendant is to stand committed until the fine is paid, or he is otherwise discharged according to law.

/s/ CONSTANCE BAKER MOTLEY
United States District Judge

549a

JUDGMENT AND PROBATION/COMMITMENT ORDER

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
----------X
UNITED STATES OF AMERICA,

v. No. 76 Cr. 253

EDWARD PASTOR,

Defendant.
----------X

In the presence of the attorney for the government the defendant appeared in person on this date, September 17th, 1976, with counsel Robert Goldman, Esq.

PLEA: NOT GUILTY

There being a verdict of GUILTY.

Defendant has been convicted as charged of the offenses of possessing Schedule III controlled substances to wit, phendimetrazine capsules and Schedule IV controlled substances to wit, phentermine, by misrepresentation, fraud, forgery, deception and subterfuge, (Title 21, United States Code, Section 843(a)(3) and Title 18, United States Code, Section 2.), and conspiracy so to do (Title 21, United States Code, Section 846), as charged in counts 1, 5 and 6.

The court asked whether defendant had anything to say why judgment should not be pronounced. Because no sufficient cause to the contrary was shown, or appeared to the court, the cour adjudged the defendant guilty as charged and

convicted and ordered that: The defendant is hereby committed to the custody of the Attorney General or his authorized representative for imprisonment for a period of SIX (6) MONTHS on count 1 and fined $5,000, sentenced to FOUR (4) YEARS on each of counts 5 and 6 to run concurrently with each other. Execution of sentence on counts 5 and 6 are suspended. Defendant is placed on probation for a period of FIVE (5) YEARS, subject to the standing probation order of this Court.

Sentence and fine imposed on count 1 are stayed pending appeal, on condition that the appeal is prompt perfected within the time allowed by the rules. If the conviction is affirmed, the defendant is to surrender within TEN DAYS after the affirmance.

The fine of $5,000 is a comitted fine and the defendant is to stand committed until the fine is paid or he is otherwise discharged according to law.

The court orders commitment to the custody of the Attorney General and recommends, that the defendant be confined to an institution with appropriate medical facilities for his heart condition.

/s/ CONSTANCE BAKER MOTLEY
United States District Judge

September 17, 1976.

NOTICE OF APPEAL

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
----------X
UNITED STATES OF AMERICA,

No. 76 Cr. 253

v.

Constance Baker Motley
(District Court Judge)

MARTIN WEINER and EDWARD PASTOR,

Defendants.
----------X

Notice is hereby given that Martin Weiner appeals to the United States Court of Appeals for the Second Circuit from the Judgment entered in this action on July 26th, 1976.

Donald Sparks, Esq.
Counsel for Appellant Weiner
344 West Front Street
Media, Pennsylvania 19063
215/565-3700

August 3rd, 1976

To:

Robert B. Fiske, Jr.
United States Attorney
for the Southern District of
New York

NOTICE OF APPEAL

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
----------X

UNITED STATES OF AMERICA,

v.

EDWARD PASTOR and MARTIN WEINER,

Defendants.
----------X

No. 76 Cr. 253

Constance Baker Motley
(District Court Judge)

Notice is hereby given that Edward Pastor appeals to the United States Court of Appeals for the Second Circuit from the Judgment entered in this action on September 17, 1976.

Kuh, Shapiro, Goldman, Cooperman & Levitt, P.C.
Counsel for Appellant
800 Third Avenue
New York, New York 10022
212/688-7000

September 17, 1976

To:

Robert B. Fiske, Jr.
United States Attorney
for the Southern District
of New York

ROBERT B. FISKE JR.